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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,802	03/30/2001	Robert Case	13207.7USU1	9154

7590 06/30/2005

EXAMINER
PASS, NATALIE

ART UNIT	PAPER NUMBER
3626	

Tom Witty
Quantech Ltd.
815 Northwest Boulevard
St. Paul, MN 55121

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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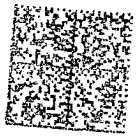

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Office Action Summary	Application No.	Applicant(s)	
	09/822,802	CASE, ROBERT	
	Examiner	Art Unit	
	Natalie A. Pass	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/17/01 & 10/04/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed 30 March 2001. Claims 1-21 are pending.

Claim Objections

2. Claims 13-14 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. It is unclear whether the dependent claims include every limitation of the parent claim. A proper dependent claim shall not conceivably be infringed by anything which would not also infringe the basic claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 recites "[a] computer-readable medium having computer-executable instructions for the method recited in claim 1." It is unclear how the step of "labeling a test sample," as recited in claim 1, line 8, can be performed by a computer-readable medium.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Coli et al., U.S. Patent Number 6, 018, 713.

(A) As per claim 15, Coli teaches a remote data input terminal having a user interface screen in communication with a server-based lab test message processor for requesting a receiving medical patient test results (Coli; column 9, lines 3-14, column 14, lines 50-56), the remote data input terminal comprising:

a user interface module for controlling the operation of the terminal and storing data within a test request and test result data store (Coli; Figure 3, Figure 4, Figure 5, column 5, lines 6-12, column 8, line 26);

a user sign-in module for accepting user identification and authentication information needed to set up the operation of the remote data input terminal (Coli; Figure 3, Figure 13, Item 1302, column 5, lines 6-12);

a patient processing module for entering patient identification information to generate a test request message to the lab test message computer needed to order a medical patient test (Coli; Figure 3, Item 306, Figure 5, column 5, lines 7-10, column 8, line 26);

a test results interface module for receiving a "report" (reads on "test result message") containing the medical test results corresponding to the test request message (Coli; Figure 12, Figure 13, Figure 18, column 9, lines 34-39); and

a message transfer module for performing data communications between the remote data input terminal and the lab test message processor (Coli; Figure 12, Figure 13, column 4, lines 50-60).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-3, 5-14, 16, 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coli et al., U.S. Patent Number 6, 018, 713 in view of Gombrich et al., U.S. Patent Number 4, 835, 372.

(A) As per claim 1, Coli teaches a method for requesting and receiving medical patient test results using a remote data input terminal in communication with a server-based lab test message computer (Coli; column 9, lines 3-14), the method comprising:

entering patient identification information for a medical patient test requested to be performed into the remote data input terminal (Coli; Figure 3, Item 306, Figure 5, column 5, lines 7-10, column 8, line 26);

entering test identification information for identifying the medical patient test requested to be performed into the remote data input terminal (Coli; Figure 3, Item 310, column 7, lines 54-55);

transmitting the patient identification information and the test identification information to the "network scheduler" (reads on "lab test message processor") in order to request the medical patient tests to be performed upon the collected test sample (Coli; Figure 2, Item 218, Figure 3, Item 320, column 9, lines 29-34);

receiving a "report" (reads on "test result message") containing test results for the requested medical patient test (Coli; Figure 12, Figure 13, Figure 18, column 9, lines34-39); and

displaying the test results from the requested medical patient test on the remote data input terminal (Coli; Figure 4, Item 402, Figure 10, Figure 13, Figure 18, column 10, lines 57-60).

Coli fails to explicitly disclose

labeling a test sample collected to perform the requested medical patient test with the patient identification information and the test identification information.

However, the above features are well-known in the art, as evidenced by Gombrich.

In particular, Gombrich teaches

labeling a test sample collected to perform the requested medical patient test with the patient identification information and the test identification information (Gombrich; column 9, lines 22-26, column 16, lines 60-64).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Coli to include labeling a test sample collected to perform the requested medical patient test with the patient identification information and the test identification information, as taught by Gombrich, with the motivations of enabling accurate and rapid transfer of patient information , thereby increasing the accuracy and/or effectiveness of drug administration and patient care, and decreasing the duration of hospital stay, and of preventing medical errors and incorrect treatment caused by inaccurate drug identification (Gombrich; column 1, lines 43-59).

(B) As per claim 2-3, 5-8, Coli and Gombrich teach a method as analyzed and discussed in claim 1 above

wherein the remote data input terminal comprises a hand-held computer having a wireless communications interface for communicating with the lab test message processor (Gombrich; Figure 25, column 22, lines 62-65);

wherein the remote data input terminal further comprises a bar code scanner for receiving data input (Gombrich; Figure 1, Item 120, column 10, lines 15-20);

wherein the entering patient identification information comprises scanning a patient bar code containing a unique patient ID (Gombrich; Figure 1, Abstract, column 9, lines 39-52);

wherein the patient bar code is located on a patient bracelet worn by the patient (Gombrich; Figure 3, Item 52, column 9, lines 39-52);

wherein the patient bar code is located on a patient chart (Gombrich, column 9, lines 39-52); and

wherein the patient identification information and the test identification information comprises one or more bar codes (Gombrich; column 9, lines 39-52).

The motivations for combining the respective teachings of Coli and Gombrich are as given in the rejection of claim 1 above, and incorporated herein.

(C) As per claims 9-12, Coli and Gombrich teach a method as analyzed and discussed in claim 1 above

wherein the method further comprises:

identifying one or more recipients for the test result message (Coli; column 14, lines 6-13); and

transmitting the one or more recipient's identity to the lab test message processor for use when sending the test results to desired recipients (Coli; column 14, lines 6-13);

identifying one or more additional recipients for the test result message (Coli; column 2, lines 15-24, column 14, lines 6-13); and

forwarding the test result message to the one or more additional recipients (Coli; column 2, lines 15-24, column 14, lines 6-13);

wherein the forwarding the test result message comprises:

transmitting the identity of the one or more additional recipients to the lab test message processor (Coli; column 2, lines 15-24, column 14, lines 6-13); and

instructing the lab test message processor to send the test result message to the additional recipients(Coli; column 2, lines 15-24, column 14, lines 6-13); and

wherein the displaying of test results comprises:

displaying one or more test result messages (Coli; Figure 4, Item 402, Figure 10, Figure 18, column 10, lines 57-60);

accepting search commands for additional test result messages corresponding to the search commands (Coli; Figure 4, Item 402, Figure 10, Figure 18, column 10, lines 57-60, column 14, lines 55-62); and

displaying the additional test result messages corresponding to the search commands (Coli; Figure 4, Item 402, Figure 10, Figure 18, column 10, lines 57-60, column 14, lines 55-62).

(D) Claims 13, 14 differ from method claims 1, 12 by reciting a "computer-readable medium having computer-executable instructions..." in the preamble. As per this limitation, Coli clearly discloses his invention to be implemented on a "computer-readable medium having computer-executable instructions" (Coli; column 6, line 66 to column 7, line 44). The remainder of claims 13, 14 incorporate the limitations of claims 1, 12, and are therefore rejected for the same reasons given above for claims 1, 12.

The motivations for combining the respective teachings of Coli and Gombrich are as given in the rejection of claim 1 above, and incorporated herein.

(E) As per claim 16, Coli teaches a terminal as analyzed and discussed in claim 15 above.

Coli fails to explicitly disclose

wherein the remote data input terminal is a hand-held computer having a wireless communications module for communicating with the lab test message computer.

However, the above features are well-known in the art, as evidenced by Gombrich.

In particular, Gombrich teaches

wherein the remote data input terminal is a hand-held computer having a wireless communications module for communicating with the lab test message computer (Gombrich; Figure 25, column 22, lines 62-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Coli to include wherein the remote data input terminal is a hand-held computer having a wireless communications module for communicating with the lab test message computer, as taught by Gombrich, with the motivations of providing a means for determining the identification and location of personnel in the field, including patients and staff members, and miscellaneous items, particularly in the case of health care institutions and more particularly nursing homes and mental institutions wherein the patients are very ambulatory and are not always cognizant of their actions (Gombrich; column 3, line 59 to column 4, line 20).

(F) As per claims 18-21, Coli and Gombrich teach a terminal as analyzed and discussed above

wherein the remote data input terminal further comprises a user ID scanning module for accepting input for the patient identification information and the test identification information (Gombrich; Figure 1, Item 120, column 10, lines 15-20);

wherein the user ID scanning module comprises a scanning module for scanning bar codes (Gombrich; Figure 1, Item 120, column 10, lines 15-20);

wherein the scanning module is an integral part of the remote data input terminal (Gombrich; Figure 12, column 35, lines 39-43); and

wherein the scanning module is an attached peripheral electronically connected to the remote data input terminal (Gombrich; Figure 12, column 32, lines 25-30).

The motivations for combining the respective teachings of Coli and Gombrich are as given in the rejection of claim 1 above, and incorporated herein.

9. Claims 4, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coli et al., U.S. Patent Number 6, 018, 713 and Gombrich et al., U.S. Patent Number 4, 835, 372 as applied to claims 1-3 and 15-16 above, and further in view of Chaco, U.S. Patent Number 5, 465, 082.

(A) As per claim 4, Coli and Gombrich teach a method as analyzed and discussed in claims 1-3 above.

Coli and Gombrich fail to explicitly disclose

wherein the remote data input terminal further comprises a pen-based user input screen for accepting input from a user.

However, the above features are well-known in the art, as evidenced by Chaco.

In particular, Chaco teaches a method

wherein the remote data input terminal further comprises a pen-based user input screen for accepting input from a user (Chaco; Figure 23, column 13, lines 39-52).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Coli to include wherein the remote data input terminal further comprises a pen-based user input screen for accepting input from a user as taught by Chaco, with the motivations of providing an apparatus for accessing and enabling a portable database having the portability of a credit card, which may be used by patients and caregivers in a hospital environment and in other analogous environment and which when coupled with an identification badge and enabled, acts to communicate data with other data processing apparatus via a ubiquitous network (Chaco; column 1, lines 9-17).

(B) As per claim 17, Coli Gombrich and Chaco teach a terminal as analyzed and discussed in claims 15 and 16 above

wherein the hand-held computer accepts pen-based input data generated using pen strokes from a stylus upon a user interface screen (Chaco; Figure 23, column 13, lines 39-52).

The motivations for combining the respective teachings of Coli Gombrich and Chaco are as given in the rejection of claims 4 and 16 above, and incorporated herein.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied references, Troyer et al, U.S. Patent Number 5,591, 974, Brown, U.S. Patent Number 6, 168, 563, Evans, U.S. Patent Application Number 5, 924, 074, Margery et al., U.S. Patent Number 6, 055, 487, Layne et al. 5, 841, 975, Killian, International Publication Number WO 9411838A, and Goldenberg, U.S. Patent Application Publication 2002/0065682 teach the environment of remote communication of test results.

11. Any response to this action should be mailed to:

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Pass whose telephone number is (571) 272-6774. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 6:30 PM. The examiner can also be reached on alternate Fridays.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (571) 272-3600.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NP

Natalie A. Pass

June 21, 2005

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600

Date Mailed: August 7, 2001

Sheet 1 of 1

FORM 1449*

INFORMATION DISCLOSURE STATEMENT

IN AN APPLICATION

(Use several sheets if necessary)

Docket Number: 13207.7USU1	Application Number: 09/822,802
Applicant: CASE	
Filing Date: March 30, 2001	Group Art Unit: 2161

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
MP	5,898,503	4/1999	Keller et al.	356	445	
MP	5,912,456	6/1999	Melendez et al.	250	206	
MP	5,946,083	8/1999	Melendez et al.	356	73	
MP	6,050,940	4/2000	Braun et al.	600	380	
MP	6,111,248	8/2000	Melendez et al.	250	239	
MP	6,111,652	8/2000	Melendez et al.	356	445	
MP	6,191,847 B1	2/2001	Melendez et al.	356	73	

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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*Substitute Disclosure Statement Form (PTO-1449)

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

ATTACHMENT TO PAPER #06162005 (#9)

Date Mailed: SEPTEMBER 30 2002

Sheet 1 of 1

FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 13207.7USU1	Application Number: 09/822,802
	Applicant: CASE	
	Filing Date: 03/30/2001	Group Art Unit: 2161

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
MP	4,835,372	05/30/1989	Gombrich et al.	235	375	
MP	5,631,844	05/20/1997	Margrey et al.	702	84	
MP	5,841,975	11/24/1998	Layne et al.	709	203	
MP	5,924,074	07/13/1999	Evans	705	2	

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
MP	WO 99/04043	01/28/1999	PCT				

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ATTACHMENT TO PAPER # 06162005 (#9)

Notice of References Cited	Application/Control No. 09/822,802	Applicant(s)/Patent Under Reexamination CASE, ROBERT	
	Examiner Natalie A. Pass	Art Unit 3626	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-6,018,713 A	01-2000	Coli et al.	705/2
	B	US-4,835,372	05-1989	Gombrich et al.	235/375
	C	US-5,465,082 A	11-1995	Chaco, John	340/825.49
	D	US-5,591,974	01-1997	Troyer et al.	250/336.1
	E	US-6,168,563	01-2001	Brown, Stephen J.	600/301
	F	US-5,924,074	07-1999	Evans, Jae A.	705/2
	G	US-6,055,487	04-2000	Margery et al.	702/84
	H	US-5,841,975	11-1998	Layne et al.	709/203
	I	US-2002/0065682	05-2002	GOLDENBERG, DAVID M.	705/2
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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	WO 9411838 A1	05-1994	World Intellect	KILLIAN, WILLIAM R	G06F 15/42
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NON-PATENT DOCUMENTS

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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
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International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : G06F 15/42

A1

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(30) Priority data:
07/973,253 6 November 1992 (06.11.92) US

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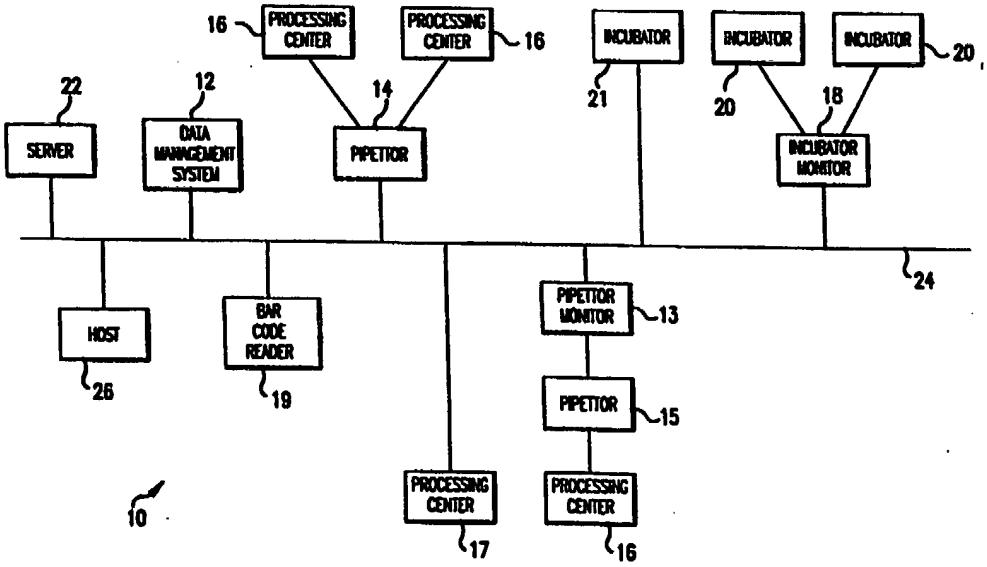
(72) Inventor: KILLIAN, William, R. ; 939 Wilshire Drive, Libertyville, IL 60048 (US).

(74) Agents: GORMAN, Edward, H., Jr. et al.; Abbott Laboratories, CHAD 0377/AP6D-2, One Abbott Park Road, Abbott Park, IL 60064-3500 (US).

(81) Designated States: AU, CA, JP, KR, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: PROCESS CONTROL SYSTEM FOR BIOLOGICAL FLUID TESTING



(57) Abstract

A system (10) for automatically testing biological fluids includes a network database (26) which holds test protocols and test results for identified samples. The system (10) tracks the samples by their identifier through the system to testing equipment (16) which is also coupled to the network (24). The system (10) records the tests performed and the times they were performed and monitors any reagents used in the test being run. In addition, the system (10) monitors any incubation of the samples and any results indicated by the test equipment (16). Information on the tests run on a particular sample, the reagents used and the results produced by the tests, are maintained a database and may be formatted into a report.

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CZ	Czech Republic	LV	Latvia	TJ	Tajikistan
DE	Germany	MC	Monaco	TT	Trinidad and Tobago
DK	Denmark	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	US	United States of America
FI	Finland	ML	Mali	UZ	Uzbekistan
FR	France	MN	Mongolia	VN	Viet Nam
GA	Gabon				

PROCESS CONTROL SYSTEM FOR BIOLOGICAL FLUID TESTING

FIELD OF THE INVENTION

The present invention relates to a process control system. More specifically, the present invention relates to a process control system used to document, coordinate, control and verify the testing of biological fluid samples, such as blood, which can be performed by automated test equipment.

BACKGROUND OF THE INVENTION

There are many reasons for testing biological fluids. Blood screening of donors at blood banks is a large and still growing market requiring accurate and

reliable testing. Donation of blood typically involves the screening for various diseases and/or foreign bodies which may be present in the blood being donated. In recent years, additional screening tests, such as HTLV-I and HCV have been mandated by law, increasing the number and complexity of tests which each blood sample must undergo. With each test, additional FDA minimum standards have also been set. Other biological fluids such as urine and saliva tests are routinely tested and/or screened for substances, diseases and chemicals.

Over the years, as both the amount of blood being donated and the number of required tests have increased, a degree of automation has occurred. Systems such as the Commander System™ by Abbott Laboratories, have partially automated many of the steps involved in blood testing.

The Commander System can be divided into four main parts: the Flexible Pipetting Center (FPC), the Parallel Processing Center (PPC), the Dynamic Incubator (DI), and the Data Management System (DMS). Under this system, a donor's blood sample is initially bar coded, linking the blood sample to a database of information about the patient, including the test(s) to be run on the blood specimen. This information is stored in a local database with the same information residing in the DMS database. The bar coded samples are then taken over to the FPC for pipetting into test wells in which the testing of the blood specimens will take place. The bar coded blood samples, stored in test tubes, have their exact position in a

holding tray entered into a database. This position information is used by the FPC in pipetting the samples.

The test wells are typically located in test trays. Each tray may contain 60 or more test wells into which blood specimens can be pipetted for testing. The FPC, at the same time that the pipetting of blood specimens takes place, can add other materials such as a diluent, as may be required by a particular test. Each tray is also bar coded. This bar code is read as soon as the tray is placed into its appropriate receptacle in the FPC. The bar code information on the tray, combined with the bar code information on each blood sample, allows accurate data gathering to track the blood sample through the testing process. In the example of the Commander System, up to four trays (and thus four tests at one test per tray) can be placed in the FPC at one time. The FPC has a maximum throughput of 900 tests per hour, highlighting the importance of accurate coordination and tracking.

Once a blood sample has been pipetted into the test wells and any required diluent has been added, the tray containing the test well moves either to the Dynamic Incubator or to the Parallel Processing Center, depending upon the tests being run on the particular blood specimens. In many cases, beads coated with an antigen or antibody, required for the test, are also added to the test wells to aid in the detection of various substances.

At the Parallel Processing Center, the bar code of the tray is again read, to insure tracking of each

individual blood sample contained in the test wells. This provides reliability in linking test results to each individual blood sample. A connection, such as a serial data connection, links the FPC to the PPC to track the blood sample through the testing which takes place at the Parallel Processing Center. In the Parallel Processing Center, washing of samples, as well as addition of reagents takes place according to a preprogrammed protocol or "recipe" for each specific test which the samples in each tray undergo. Should there be any problem with reading the bar code , an operator may physically enter the tray identification number to ensure accurate tracking. The PPC indicates the completion of the processing pass by way of an audible tone. The PPC also reads the test results by way of a spectraphotometer. The test results, which are linked to a particular blood sample, by way of the bar code, are then ported over to the DMS via a connection, such as a serial data connection.

The Dynamic Incubator provides incubation and/or agitation for samples undergoing tests which require these steps. The DI of the Commander System can incubate up to eight trays at various possible preset temperatures (although only one temperature at a time may be set). The DI also provides for entering specific times for each individual tray placed in the incubator. When the entered time has elapsed for each individual tray, a signal, such as an audible alarm combined with a display, will indicate which tray has completed its incubation/agitation.

The Data Management System takes the information provided to it from the FPC and PPC to provide a report of the test results for each blood sample.

Although blood testing systems, such as the Commander System, have provided a degree of reliability, accuracy and consistency in the blood testing process, the increase in amount of blood donated, the number of tests which can be run for each donor, and the ever increasing government standards, including the Good Manufacturing Practices (GMP), make even better safeguards and better control and documentation of the entire process more and more desirable. Further, the increase in the number of tests which can be performed or are required to be performed, means additional chemicals and reagents which must be closely monitored for factors such as expiration dates. This raises the possibility of operator error in selecting, tracking and operating the tests. Lastly, the ability to monitor the integrity of each test and the ability to determine whether multiple tests (such as retests to provide statistical accuracy) are required are also desired features.

SUMMARY OF THE INVENTION

The present invention is embodied in a testing system for biological fluids which includes means for transferring the fluids from a test tube or holding container to a test site, such as a test cell in a testing

tray. Means are also provided for testing the biological fluid samples for a number of desired tests. Control means, such as a computer, coordinate the transfer and testing of the biological fluids, as well as tracking these operations. Lastly, connection means are provided, allowing communication among all of the devices.

In an exemplary embodiment of the present invention, a Pipetting System is used to deliver blood samples, for example, to a test well in a test tray which is the test site. Either or both a Processing Center and an Incubator (under control of an Incubator Monitor) are used as required by the specific test which the blood sample is undergoing. A computer, such as a personal computer, coordinates the testing, tracking bar code information, directing equipment and human operators to ensure that the proper test procedures are carried out and the proper chemicals and reagents are used. At the same time, the computer documents whether each test has been carried out as specified, including whether the test equipment has been calibrated and whether the chemicals and reagents used are not beyond their expiration dates. A network, such as an Ethernet™ network, connects the various pieces of equipment to the computer for effective communication among each piece of equipment and the control computer.

BRIEF DESCRIPTION OF THE FIGURES

The present invention is described by way of nonlimiting example with reference to the following figures in which:

Figure 1 is a system diagram of an exemplary testing system of the present invention;

Figure 2 is a program flow diagram which illustrates the operation of the TIP/TRAY LOT NUMBER SPECIFICATION routine;

Figure 3 is a program flow diagram which illustrates the operation of the MASTER LOT INFORMATION routine;

Figure 4 is a program flow diagram which illustrates the operation of the VIEW EXPIRED MASTER LOT INFORMATION routine;

Figure 5 is a program flow diagram which illustrates the operation of the MASTER LOT INFORMATION routine;

Figure 6 is a program flow diagram which illustrates the operation of the assay section of the PIPETTING RUN SETUP routine;

Figure 7 is a program flow diagram which illustrates the operation of the control section of the PIPETTING RUN SETUP routine;

Figure 8 is a program flow diagram which illustrates the operation of the destination object specification section of the PIPETTING RUN SETUP routine;

Figure 9 is a program flow diagram which illustrates the operation of the diluent and control placement section of the PIPETTING RUN SETUP routine;

Figure 10 is a program flow diagram which illustrates the operation of the volume verification of diluent and control section of the PIPETTING RUN SETUP routine;

Figure 11 is a program flow diagram which illustrates the operation of the PIPETTING routine;

Figure 12 is a program flow diagram which illustrates the operation of the MONITOR AND FUNCTION ENTRY routine;

Figures 13a and 13b are program flow diagrams which illustrate the operation of the BEGIN TRAY INCUBATION routine;

Figures 14a and 14b are program flow diagrams which illustrate the operation of the TRAY INCUBATION COMPLETE routine;

Figures 15a and 15b are program flow diagrams which illustrate the operation of the ALARM STATE routine;

Figure 16 is a program flow diagram which illustrates the operation of the PRINT INCUBATOR DATA routine;

Figure 17 is a program flow diagram which illustrates the operation of the PRINT INCUBATOR MONITOR ERROR LOG routine;

Figure 18 is a program flow diagram which illustrates the operation of the TIME OUT OF COOLER routine;

Figure 19 is a program flow diagram which illustrates the operation of the COVER SEAL LOT NUMBER ENTRY routine;

Figures 20a and 20b are program flow diagrams which illustrate the operation of the BEAD ADDITION routine;

Figures 21a and 21b are program flow diagrams which illustrate the operation of the CONJUGATE RECONSTITUTION routine;

Figures 22a and 22b are program flow diagrams which illustrate the operation of the OPD PREPARATION routine;

Figure 23 is a flow chart diagram which illustrates a three-pass test which may be performed using the system shown in Figure 1;

Figure 24 is a program flow diagram which of the PREPARE REAGENTS routine shown in Figure 23;

Figure 25 is a program flow diagram of the CHECK VALID TRAY routine which is part of the PROCESS TRAY routines shown in Figure 23;

Figure 26 is a program flow diagram of the APPROVE TECHNICIAN I.D. routine which is part of the PROCESS TRAY routines shown in Figure 23;

Figures 27a and 27b are program flow diagrams which illustrate the remaining steps in each of the PROCESS TRAY routines shown in Figure 23;

Figure 28 is a flow diagram which illustrates a collation of results by the DMS;

Figure 29 is a flow diagram which illustrates exemplary report options;

Figure 30 is a flow diagram which illustrates exemplary batch record and statistical reports;

Figure 31 is a flow diagram which illustrates a test which may be performed using the system shown in Figure 1.

DETAILED DESCRIPTION OF THE INVENTION

There is shown in Figure 1 an exemplary system for testing biological fluids or Process Control Network 10. Testing system 10 comprises a Data Management System (DMS) 12, a Pipettor 14, a Processing Center (PC) 16, an Incubator Monitor (IM) 18 and an Incubator (I) 20. There are multiple units of Processing Center 16 and Incubator 20 shown to illustrate that more than one of these units (as well as the others) can be connected in system 10. There is also shown in figure 1 a Pipettor 15 which is connected to a Pipettor Monitor 13 to illustrate that the "intelligence" for a pipettor can be separate from the pipettor. Similarly, Incubator 21 is shown as being directly connected to network 24 to illustrate that the intelligence or front end processing can be a part of the incubator. Other configurations, not shown, are possible depending upon the needs for system 10 by the user.

Bar Code Reader (BCR) 19 is shown for reading bar code information and sending the information out onto network 24. A bar code reader can also be connected to a particular device for entering bar code information at particular locations on the system and/or times in the process.

Also shown is a host computer 26, server 22 and a network 24. Host computer 26 may be a bulk storage computer or mainframe for holding a large database of patient information and results from past tests. Network 24 may consist of an Ethernet network for example, which connects each of the devices to server 22. A network such as an Ethernet requires network cabling, network cards, a

network operating system and assorted hardware as is understood by those skilled in the art. Numerous other types of networks can be used to allow communication between the various devices, making up the present invention. Similarly, server 22 may consist of any computer suitable for operating the network being used. A personal computer using a 386, 486 or similar microprocessor chip can be used as server 24. RISC workstations or mini or mainframe computers can also be used to operate the software and control the network which connects all of the devices of the present invention to provide communication.

The components of the present invention are described by way of figure 1 using those components of the Commander System (incorporated by reference, herein) which are applicable to the present invention. This is in no way meant as a limitation of the equipment which can be used. For example, pipetting systems other than the Flexible Pipetting Center can be used, controlled and tracked in accordance with the present invention. Similarly, incubators other than the Dynamic Incubator may be used. The following are Abbott Laboratories List Numbers for components which can be used in an exemplary embodiment of the present invention:

Item	List #
Flexible Pipetting Center 14	3A46-01
Personal Computer 12	3A46-70
Control Software (not shown)	3A46-87
Bar Code Reader 19	3A46-28
Dynamic Incubator 20	6210-01
Parallel Processing Center 16	6208-01

DMS 12 is used to enter and coordinate information regarding the tests to be run for a given sample. The DMS relays this information via network 24 to the devices which carry out the testing steps. DMS 12 operates a database, such as Oracle™ Version 6.X to track, store and answer system requests for information.

DMS 12 evaluates the information for the samples (or requests to test samples) and translates this into the actual tests to be carried out. If a sample is to be tested for diagnostic purposes, the appropriate tests would be ordered, which may differ from the tests ordered for a blood donor screening. For instance, a blood sample from an HIV patient would not be subjected to routine screening tests, but rather to tests related to the HIV condition which have been predetermined and entered into system 10. Conversely, a normal blood donor sample would be given a preselected group of tests regardless of the condition of the donor, because it is a screening process.

Reagents are used in testing a biological fluid sample. Reagents are logged into a reagent library containing information on each reagent lot, including expiration dates, lot numbers and amounts of reagent received. The reagent library is a database of information stored on a computer. The database can be set up using commercial products, such as Oracle™. It is also possible to provide any particular information necessary for use of

the reagents, such as optimum storage and operation temperatures, and parameters to use to normalize the results of tests performed using the reagents to results obtained from an ideal reagent. The amount of information logged for any reagent lot would be selected by the user and may depend upon factors such as the tests being run and/or government regulations.

In an exemplary embodiment of the present invention, the reagent information accompanies each lot of reagents. Each bottle of reagent has a bar code label affixed to the bottle, linking the bottle to the master lot information contained on the sheet which accompanies each kit of reagents. The lot of reagents and the master lot information sheet comprises a reagent kit. As a reagent kit is received, the bar code information from the master lot information sheet is scanned into the network via a bar code reader, such as BCR 19. This information is then stored on the network, in a local memory storage device, such as a hard disk drive, where it can be made available to all equipment via network 24.

For example, the reagent kit information can be read into the system using a bar code reader attached to aPipettor 14 and stored on the hard drive in the control computer of Pipettor 14. Another embodiment may have the information stored at a central location such as server 22. These and other variations will be understood by those skilled in the art.

A bar code reader may be separate from or attached to a Pipettor 14. As the system of the present invention is connected via a network, the bar code information can be read in from anywhere on network 24 and then stored at its proper location.

Once the master lot information is stored in system 10, reagents can be used until an expiration date, for example, is noted by system 10. At this point, the remaining reagents in the lot, if any, would be removed and a new reagent kit brought in. If system 10 detects a reagent bar code which is not associated with an approved reagent, the operator will be alerted and the processing halted. At this point, another approved library lot must be selected for use or a new acceptable lot must be loaded into the database such that it can be subsequently used for processing.

Automatic test ordering can take place with the present invention through host computer 26. Host computer 26 stores the original donor information. It is not necessary and often not advisable for a testing facility using the present invention to possess all donor information which may include, for example, the name of the patient. The present invention only requires information necessary to carry out the testing of biological fluid samples such as blood. Host computer 26 can access DMS 12 directly through network 24, requesting specific tests for a particular blood sample. Host computer 26 can also be connected to DMS 12 via a serial connection (not shown), as opposed to the network connection. As DMS 12 initiates

and coordinates the testing process, there would be no need for the individual pieces of test equipment to access host computer 26 directly or vice versa. It is nevertheless possible for all equipment to access host 26 directly. In any event, the particular tests designated for a given blood sample would be communicated from host computer 26 to DMS 12 for storage and eventual execution by system 10.

Pipettor 14 is used to pipet an aliquot of sample from a test tube into a test site. Aliquots of sample are typically in the range of less than 300 micro liters, but amounts may vary, depending upon the test involved. In this example, the test sites are the test wells of a test tray which fit into receiving portions of Pipettor 14, Processing Center 16 and Incubator 20. In this example, each test tray has approximately 60 test wells and thus 60 samples can undergo the test being applied to the tray.

For this exemplary embodiment, Pipettor 14 as was used in the Commander System is being described. This pipetting system uses a single pipet with a removable pipet tip. It is well within the scope of this disclosure that other pipetting systems can be used within this invention. Other pipetting systems may use multiple pipets which can pipet up to 12 samples at one time. Many bulk applications use a multiple pipet system for delivery of sample to multiple test sites.

Pipettor 14 polls DMS 12 to obtain information necessary to pipet an aliquot of sample into the proper

number of test sites. For example, if four tests are desired, then four trays would be placed in Pipettor 14 (where each tray of test wells undergoes one test protocol). DMS 12 communicates with Pipettor 14 over network 24, providing the test information for each sample to Pipettor 14. This can be done for each individual sample or for blocks of samples. Pipettor 14 pipets an aliquot or portion of the sample into one test well per tray to provide four tests. Should fewer tests be necessary for a particular sample, Pipettor 14 would only pipet according to the number of tests necessary. Other samples may require fewer or more tests. By having this information in DMS 12 and, having Pipettor 14 in communication with DMS 12, appropriate tests are ordered for each sample. An aliquot of a given sample is then pipetted to the proper test site in the proper tray automatically. There is thus, no requirement of operator intervention to allocate the sample to the proper test trays nearly eliminating errors caused by operator intervention. This is the implementation of the sample profile originally downloaded from the host or entered into the system.

Pipetting can begin at any time in the process subsequent to downloading sample information from host 26 to DMS 12. The reagents are bar coded and entered into the system as described above. Although the present embodiment is described using bar codes, other methods of encoding and labelling could be used to provide easy entry and tracking of samples, trays and reagents. Each Pipettor 14 checks to make sure that proper, unexpired reagents (such as

calibrators, controls, or other reagents) are present before it begins pipetting a sample into the designated test sites of the trays. If there are invalid reagents due to situations such as an expired reagent lot, no pipetting will occur. Each reagent volume will be checked prior to pipetting to ensure adequate volume is present for the batch.

Further, in running the test, it is a common practice to use control specimens along with the sample specimens. The control specimens are used to ensure that the reagents and/or other testing facilities are working properly to identify the substances for which the samples are being tested. It is typical to run a control at the beginning of a group of trays being subjected to the same test for a particular substance or disease. Thus, Pipettor 14 also makes sure that there is sufficient control specimen, before a test is commenced.

The test tubes of samples are loaded onto Pipettor 14 and an automatic bar code reader (not shown) scans the sample tubes. It then polls DMS 12 as to which tests are appropriate for the given samples. This information, combined with the information concerning the reagents which are loaded on Pipettor 14 at the present time, determine the tests which the samples will be prepared for on Pipettor 14 at that time. For testing situations which require multiple runs to ensure proper statistical results, system 10 would be advised of this through network 24 with information from DMS 12 and

instruct Pipettor 14 to pipet the aliquots of samples into multiple test sites as appropriate.

In essence, the present invention removes the need for personnel to manually check reagent expiration dates, presence of proper reagents in the system, proper reagent volume and other factors. Further, the ability to run multiple replicates of a given sample within a batch alleviates the need to sort sample tubes into those requiring multiple tests and those that do not. The use of the bar codes combined with the communication between master database and testing equipment allows preparation of a variety of aliquots of samples requiring different tests.

Processing reagents for PC 16 may take the form of conjugate, acid, OPD (o-Phenylendiamine, a color tag), or coated beads, for example. As each reagent is loaded onto a Processing Center 16, the bar code information for the reagent is scanned using a bar code scanner attached to each Processing Center 16 or Incubator Monitor 18.

The reagent library is stored on system 10. It can be stored at a central location, such as server 22 or DMS 12 or it can be distributed at multiple locations such as Pipettors 14 and Incubator Monitors 18. As the information is entered, it is also checked to make sure that the reagents have not expired. This checking will take place prior to use on each batch, although a user could designate different check times depending on the tests being run.

As is shown in Figure 1, there are multiple Processing Center 16 units which can be connected to each Pipettor 14 and/or network 24. In the exemplary embodiment shown in Figure 1, only Pipettor 14 is connected to the network. It is wholly within the scope of this invention and disclosure that any and all devices can be directly coupled to the network for communication between the particular devices and DMS 12.

In this exemplary embodiment, Processing Center units 16 are connected to network 24 via Pipettor 14, reducing the need for network communication equipment in the Processing Center units 16. A Processing Center 17 is, nevertheless, illustrated to show that such a configuration can be used. It is also possible for any Processing Center 16 to poll network 24 for necessary information stored in any Pipettor 14. This allows constant and accurate tracking, as well as reliable testing at any point in the testing process without the need for operator input of testing information. Each device can request and receive the information it needs to carry out its functions.

With pipetting complete, the tray of test sites is transported to a Processing Center 16 for processing. Trays may be transported by operator or mechanical means, such as a conveyor belt. This applies to the transport of trays (and thus test sites) between any devices in system 10. As the tray enters Processing Center 16, the bar code on the tray is automatically read and a request is sent out over network 24 for assay information. The pipetting information can also be stored locally at a particular

Pipettor 14 for communication to Processing Center 16 units. Processing Center units 16 use this information to carry out the assays using the reagents loaded into each Processing Center 16.

In many instances, it is necessary to provide several passes through a Processing Center 16 to complete the assay protocol steps for a particular test. It is also typical for tests to undergo incubation after each pass through a Processing Center 16.

For instance, after a first pass through a Processing Center 16, it may be necessary to incubate the tray of test sites. At this point, the trays would be transported from Processing Center 16 to an Incubator 20 where the tray bar code is scanned (either at Incubator 20 or IM 18) prior to placing the tray in one of the selected tray slots. Incubator 20 uses the network to check the tray status and confirm incubation requirements. In the present embodiment, information is communicated to an Incubator 20 through IM 18. In effect, IM 18 possesses the "intelligence" and processing capability, similar to the computer controlling each Pipettor 14. The incubation requirements are based on the particular samples being tested and the particular test being run for those samples. The necessary incubation time and temperature would be part of the profile for a particular test. A IM 18 requests the information linked to the bar code through network 24. The request would obtain the information from a Pipettor 14 or other location where the information is stored.

Once a tray is inserted into an Incubator 20, its position is confirmed by scanning a bar code adjacent to the incubation slot and beginning incubation. An Incubator 20 will automatically be set to the proper incubation time, temperature and agitation of the tray (if necessary) by IM 18. IM 18 will constantly check temperature to confirm that all specifications for the tests have been met.

One of the features of the present invention is the ability to catalog and manage all of the data which is present during the testing of aliquots of samples. Information such as incubator serial number, time of incubation, reagent lot, etc. are now all stored and can be retrieved at any time. For instance, if at a later time it is determined that a particular lot of reagents was actually defective, all testing done with that lot can be immediately identified and flagged as invalid. Also, should testing requirements change, a system wide change can be implemented at any time. This would also allow the flagging of samples done under prior methods which may prove invalid under new specification. Data is available to the system during the testing process. The length of time the information is stored on system 10 depends upon the particular user and capacity of equipment such as hard drives, large volumes of information may be deleted at selected time intervals or archived in an archive storage device (not shown). There is little need for operator intervention as the desired information is already programmed into the system for retrieval and monitoring. Operator input is basically limited to scanning bar codes

where this is not automatically done and entering operator identification codes as steps are performed.

Because test results are a part of the database information, testing which requires multiple runs for statistical purposes can be automatically implemented once the first test results are obtained. Once a first positive result is obtained, the existence of this result in the database will cause system 10 to automatically run the necessary additional test for the sample, the next time the sample is loaded into Pipettor 14.

Once all testing is complete, the information from the testing cycle can be put into a report sorted and restricted as is understood by those skilled in the art. This information can be passed along the network to other facilities, maintained in a data storage facility, printed out by a printing device, or displayed on a display device.

The following routines are illustrative of the exemplary embodiment and should not be read as solely limiting the operation of the various components of the present invention.

There is shown in figure 2 a routine which addresses the specification of the tip or tray lot numbers. In step 32, either the tip or tray lot number is selected from the system menu. The exemplary embodiment of the present invention is menu driven for ease of operation by the operating personnel. Accordingly, many of the functions will be carried out through selection of menu

choices. Implementation of a menu drive selection system as well as other systems, will be understood by those skilled in the art.

In step 34, the operator selects the pipettor to be used if more than one pipettor is configured in the system. In step 36, the operator would enter his or her operator identification information. This is for tracking purposes, so that the personnel carrying out the various tasks requiring operator interface can be tracked. In step 38, an electronic work sheet (configuration menu) is produced for the operator listing the locations of all disposables and their current lot numbers. Any lot numbers that have changed should be updated on the system. It should be noted that the entry of lot numbers must take place prior to their use in system 10. In step 40, the selections are saved into system 10, updating the database of information which is stored on system 10 at an appropriate storage location.

There is shown in figure 3 a routine for viewing the master lot information. In step 44, the operator selects the master lot information choice from the main menu. In step 46, the operator selects the view master lot choice from the master lot information menu. This is a menu nested within the main menu. In step 48, the operator goes to the next nested window wherein the master lot which is to be viewed is selected from a list of all master lots available in the system. In step 50, the operator views the list of all information associated with the desired master lot. Then in step 52, the user may delete the

master lot and all information associated with it. This will remove the master lot from the logical area where it could be used by system 10. Deleting of any information will typically be password controlled, at the option of the system supervisors. Master lot information may be deleted if at any time, for example, the quality of the reagents in the master lot becomes questionable.

There is shown in figure 4 a routine for viewing expired master lot information. In step 56 the operator selects the master lot information choice from the main menu. In step 58, the operator selects to view the expired master lot choice from the master lot information menu. In step 60, the operator receives a report of all expired master lots in the system. This can be either on screen (not shown) or by a printout of a printer (not shown) attached on the network. Finally, in step 62 the user is given the option of deleting the expired master lots. Again, for tasks such as this, password control will probably be desired.

There is shown in figure 5 a routine for recording master lot information. In step 66, the operator selects master lot information from the main menu. In step 68, the operator selects the record information option from the master lot information menu. In step 70, the operator enters the password if password protection is enabled. In step 72, the operator enters his or her operator identification code to maintain tracking of users. In step 73, the master lot number from the kit card is entered. This card is enclosed with the reagent kit by the

manufacturer. As previously described, this card will contain pertinent information to the reagent lot being entered. In step 74, a determination is made as to whether the master lot information has already been entered. If so, the current information is displayed and processing moves to step 84. Otherwise, processing continues to step 76 where the test identifier for the master lot is entered from the kit card. The test identifier provides the information for the tests to be run with the reagents from the kit. In step 78, the number of components in the kit is then determined. In step 80 the lot number is entered for each component of the kit. In step 82 the expiration date is entered for each component of the kit. In step 84 a loop back to step 78 is performed until all of the component information from the kit has been entered. In step 86 the operator requests confirmation of the components in the kit to check against the kit listing. In step 88, the master lot information is stored in a database which is accessible via network 24. In step 100, the master lot summary report is printed.

The routine for an exemplary assay selection is shown in Figure 6. The pipetting run setup begins with the assay selection. In step 104, the pipetting setup is selected from the menu. In step 106, the operator's I.D. is entered for the pipetting run, about to begin. In step 108, the sample tube inner diameter is entered. This provides the necessary information for Pipettor 14 which in the exemplary embodiment is the Flexible Pipetting System 14 which uses stepper motors to take the sample fluid and deliver it to the test sites. In step 110, the bar code

mode is entered for reading bar code information. In step 112, a request is made to select the tray map print option, should the operator desire to print out a map of the tray. In step 114, the pipetting type is selected; for example batch or random mode. In step 116, the selection of the assays to be pipetted during the run is selected. In step 118, a decision is made whether the assays can be pipetted together. If so, processing moves to step 122. In step 120, a decision is made whether assays can be pipetted together and if not, processing returns to step 116.

In step 122, the number of destinations for each assay is determined. This corresponds to the number of tests which will be run on each fluid sample. In step 124, it is determined whether Pipettor 14 is being run in the total process control (TPC) mode and whether Pipettor 14 is in the record or verify mode. If so, the master lot number for the assay is entered.

To allow for flexibility, network 24 may be configured for total process control (TPC) OFF/ON. If ON, the user may then further turn ON/OFF various features as he or she desires. For example, one user may want the system to track and verify reagent status but may not wish to enter and track technician identification.

Furthermore, the user may want to run certain tests under total process control, as this was defined by configuration described above, but they may want to run other tests without total process control. In order to

provide for this flexibility, the user may define modes for each assay as follows:

Normal Mode - no features of total process control are enabled;

Record Mode - for those features turned ON, system 10 will record and track data as it is entered. However, this data will not be verified. For example, if a reagent lot number is entered, it will be recorded but not verified in the reagent library. The user may also choose to enter no lot number in which case the system will move on to the next step without alarming the user.

Verify Mode - for those features turned ON, the system will record, track, and verify data entered. If data is found to be unacceptable, or if no data is entered, the user will be notified with an alarm and be prompted to correct the problem. The user may choose to override the alarm state, in which case the data is then only tracked and is flagged as a deviation.

In step 126, if the master lot number does not turn up, the operator will be questioned as to whether this is a reagent qualifying run. If so, the information concerning this assay will be flagged to indicate that it is in qualifying mode. This will provide calibration and testing information for the system. In step 128, if the TPC mode is ON, the verify mode is ON, the qualify mode is OFF, and the master lot number does not exist in the database, the system will provide a warning message to the

user. An option of overriding the warning is provided allowing this step of the assay to be processed in record mode. If the operator chooses not to continue, processing will return to step 116. In step 130, a determination is made if the requested number of destination objects for each assay causes the destination objects not to fit on the platform. In such a case, processing also returns to step 116. In step 132, the platform configuration is saved.

In Figure 7, there is shown the control section routine. In step 134, the controls to be pipetted for each destination object during a run are selected. The controls are used to verify the accuracy of the testing equipment and reagents. In step 136, the control selection is saved.

In Figure 8, the destination object specification is provided. In step 138, a determination is made as to whether the assay has a reagent coated destination object, the system is in TPC ON mode and the assay mode is set to record or verify. Under such conditions, the operator is asked to enter the lot number of the destination object. In step 140, the user enters the actual destination object. In step 142, if the destination object I.D. exists in the system, another message is provided and processing returns to step 140. In step 144, a new destination object I.D. is created in the database. In step 146, the user is asked to place the destination object on the platform and confirm that proper placement has taken place. In step 148, a determination is made as to whether there are more destination objects that need to be placed. If so, processing returns to step 138.

Otherwise, processing continues to the routine shown at Figure 9.

Figure 9 shows the routine for the diluent and control placement. In step 150, a screen is displayed indicating the location for all reagents and controls on the platform of Pipettor 14. In step 152, a determination is made as to whether the system is in TPC ON mode and the assay mode is set to record or verify. If so, a request of the lot number for the diluent or control bottle is made. The user may override these modes. In step 154, the I.D. of the control (should a control be placed at this time) is made against the master lot list. In step 156, if the I.D. does not match an entry in the list, the operator is provided with an error message and processing returns to step 152. In step 158, if the expiration date of the control has been reached, the operator is provided with an error message and processing proceeds to step 168. In step 160, a determination is made as to whether the master lot of the control is consistent with the other controls in use for this assay. If inconsistent, the operator is provided with an error message and processing jumps to step 168. In step 162, the operator is asked to place a control bottle in the proper selected position. In step 164, the operator is instructed to bar code the position of the control bottle. If the position differs from the expected position, the operator is provided with an error message and this step is repeated. In step 166, processing jumps back to step 152 and is repeated for all remaining diluents and controls for this pipettor run. If all diluents and controls have already been assigned positions, processing

proceeds to step 174. In step 168, the operator is given the opportunity to override the error message. If this option is taken, processing returns to the earlier. If the error is not overridden, processing proceeds to step 170. In step 170, the operator is requested to remove the control bottle from the platform. In step 172, processing goes back to step 152. In step 174, the platform configuration is saved and in step 176, a determination is made as to whether the dilutor should be primed.

There is shown in Figure 10 a routine for volume verification of diluents and controls. In step 178, a determination is made as to whether the TPC mode is in the off position. If so, processing proceeds to step 214. If not, a new pipet tip is picked up from the rack in step 182. In step 184, the fluid level in the diluent bottle is sensed to determine the amount of diluent which is present. In step 186, the number of wells that could require diluent for this particular assay is computed. In step 188, a warning is provided should the amount of diluent be insufficient to fill an entire tray as determined in step 186. In step 190, the operator is given the option of replacing the bottle of diluent.

Should the operator choose not to, processing proceeds to step 198. In step 192, the operator is asked to remove the diluent bottle from the platform. In step 194, if the assay mode is set to verify or record, the operator is asked to enter the lot number for the diluent. In step 196, if the assay mode is set to verify, the lot number on the master lot list is verified. If incorrect,

the operator is given an error message and processing returns to step 192. If correct, the user is instructed to place the bottle of diluent on the platform. In step 198, if more diluents are present, processing returns to step 180. Otherwise, processing continues to step 200.

In step 200, a determination is made as to whether the assay used in the control bottle is set to normal mode. If so, processing proceeds to step 212. Otherwise, processing continues to step 202 where a new tip is picked up from the rack. In step 204, the fluid level in the control bottle is sensed to determine the amount of fluid present. In step 206, the tip is dropped into the waste bin for disposal. In step 208, if sufficient fluid is available in the control bottle to pipet all control positions for this control in this assay, processing continues to step 212. In step 210, a determination is made as to whether the fluid available is adequate to pipet all control positions. Pipettor 14 will keep track of the bottle position and the amount of fluid required. Volume verification is continued for the remaining bottles.

In step 212, a determination is made as to whether there is sufficient fluid and whether there are more control bottles to fill. If so, processing goes back to step 200 for the remaining control bottles. In step 214, if all bottles have sufficient volume, pipetting begins with the routine set forth in Figure 11.

In step 216 of figure 11, a determination is made as to whether any bottles do not have sufficient

has an available slot, the IM 18 sets the timer for the slot to the time specified. If no Incubator 20 slot is available, the IM 18 gets the time for room temperature incubation from PC 16 by accessing the first row OPD dispense time stamp. In either instance, control is transferred to step 284.

At step 278, if an Incubator 20 is available but is not set up for the present protocol requirements for the tray, IM 18 will set the mode and temperature for the available Incubator 20 and will not allow Incubator 20 to be used until it has reached its set point. At step 280, IM 18 times-out the selected Incubator 20. If it does not reach its set point in a predetermined time limit, the ALARM STATE routine is invoked. Otherwise, when Incubator 20 reaches its set point, IM 18 will set the timer for the slot and instruct the technician to insert the tray.

At step 284, if this is a conjugate or OPD incubation, IM 18 will prompt the technician to verify well volumes and place a cover seal on tray. At steps 286 and 288, the technician either places the tray into the identified slot and pushes the button next to the slot or places it on the counter near a room temperature probe and pushes the ROOM TEMP button on IM 18 if the incubation is to be at room temperature. In response to this last step, IM 18 stores the incubation start time, Incubator 20 serial number, IM 18 software revision module the slot number, mode, temperature used and tray number in its internal memory. At step 292, IM 18 also passes this information to the DMS II through network 24. Finally, at step 294, IM

18 returns control to the MONITOR AND FUNCTION ENTRY routine, described above with reference to Figure 12.

Figures 14a and 14b describe the tray incubation complete routine. The first step in this routine, Step 298, IM 18 emits an alarm indicating that a tray needs to come out of its incubator. At step 300 the technician enters his identification code. At step 302, IM 18 verifies that the identification code is that of a qualified technician.

If, at step 304, the technician is not identified as qualified, IM 18 notifies the network of the unqualified technician status and returns control to step 298 until a qualified technician identification code is entered. If, at step 306, the technician is identified as being qualified, he or she is allowed to remove the tray from the Incubator 20 slot that is emitting the alarm. The next step in this process is step 308 of Figure 14b. At this step, the technician wands the bar code on the tray. At step 310, the technician pushes the button next to the slot where the tray was just removed or pushes the room temperature incubation button if the tray was being incubated at room temperature. At step 312 IM 18 receives the incubation stop time and from this calculates elapsed incubation time. At step 314 IM 18 stores the stop timer value for the tray number that was removed from the Incubator 20 slot. At step 316 IM 18 reports the stop time and elapsed time for the tray number to the network. At Step 318, IM 18 stores the minimum and maximum incubation temperatures and the mean temperature for the tray number.

At step 320 IM 18 notifies network 24 of these temperatures. Step 322 completes this routines by returning to the MONITOR AND THE FUNCTION routine.

The ALARM STATE routine is described with reference to figures 15a and 15b. At the first step in these figures, step 324, IM 18 goes into a severe alarm state which causes IM 18 to emit an alarm sound which is different than the alarm ofIncubator 20. At step 326, IM 18 stores an indication of the alarm, IM 18 serial number, and the serial number of Incubator 20 which caused the alarm.

Next, at step 328, IM 18 notifies network 24 of the type of alarm, either rotate, air flow, or temperature. IM 18 then sends its serial number and the serial number of Incubator 20 to network 24. At step 330, IM 18 determines whether another Incubator 20 is available to receive the trays in the failing Incubator 20. At step 332 if no other Incubator 20 is available then IM 18 voids all the associated trays and returns to the monitor and function entry routine, described above with reference to figure 12. Prior to returning to the monitor and function entry routine, IM 18 notifies network 24 of the voided trays at step 334.

At step 336, a substitute Incubator 20 has been found. Accordingly, IM 18 notifies the technician of which trays to move and where they are to be moved. At step 338, the technician is prompted to enter his identification code. At step 340 IM 18 verifies the identification code

against the network database qualified technicians. If, at step 342, the technician is not qualified to move the trays to the new incubator, IM 18 will notify the network of the unqualified technician status and transfer control to step 336 which will again prompt for a technician ID number until a qualified technician is found.

The ALARM STATE routine continues at step 344 of Figure 15b. At this step, once a qualified technician has been located, he is allowed to remove a specified tray from the failing Incubator 20. At step 346, the technician wands the tray to read its bar coded identification number. At step 348, the technician inserts the tray into the specified slot of the new Incubator 20 and wands the tray position numbers. At step 350, the technician pushes the tray slot button next to the specified slot. At step 352, IM 18 continues to monitor the tray in the new documented position and stores an additionalIM 18 serial number, Incubator 20 serial number IM 18, software revision number, slot number, mode, temperature and tray number in its local memory. At step 354 IM 18 notifies network 24 of this data. At step 356 control is returned to step 344 which repeats the above steps until all the trays have been moved from the failing Incubator 20 to the newly found Incubator 20. At step 358 IM 18 returns to the function which invoked the alarm state routine or returns to the MONITOR AND FUNCTION ENTRY routine.

Figure 16 describes the function performed by the PRINT INCUBATOR 18 DATA routine. As described above, this routine prints data stored in a specified Incubator

20. The first step in this routine, step 360, is to prompt the technician to specify which Incubator 20 the data is to be read from. At step 362, the technician enters this Incubator 20 identification number. At step 364, IM 18 prints to a printer, temperature, mode, and assay by tray slot and the time that the tray is due to come out for each tray in the dynamic integrator. At step 366, IM 18 returns to the MONITOR AND FUNCTION ENTRY routine.Figure 17 describes the PRINT CDIM ERROR LOG routine. At step 368, this routine causes IM 18 to print the error log which includes at least the last 100 error codes, to a printer. At step 370 IM 18 returns control to the FUNCTION AND DATA ENTRY routine described above with reference to figure 12.

Figure 18 describes the time out of cooler routine. In the first step of this routine, 372, IM 18 prompts the technician to enter his or her identification code. At step 374, IM 18 verifies the entered identification code against the database of qualified technicians. At step 376 if IM 18 determines that the technician is not qualified, it notifies network 24 that an unqualified technician has attempted access and returns to step 372 to request the technician to enter a valid ID.

Once a valid technician ID has been entered, at step 378, the technician is prompted to wand the lot number of the conjugate or bead container which is to be removed from the cooler. At step 380, IM 18 records the time at which the conjugate bead container was removed from the cooler and stores this and the associated lot number in its local memory. At step 382, IM 18 notifies network 24 of

this data. Next, at step 384, IM 18 polls network 24 to determine the validity of this lot number. At step 386 if the lot number is determined to be invalid, then IM 18 displays a message to that effect and returns control to step 378 to prompt the technician to wand another container. At step 388, IM 18 sets a timer on network 24 which prohibits the use of the removed container until 30 minutes after the container has been removed to allow the conjugate or beads to come up to room temperature. At step 390, the routine returns control to the MONITOR AND FUNCTION ENTRY routine.

Figure 19 shows the program flow for the COVER SEAL AND LOT NUMBER ENTRY routine. The first step in this routine, step 392, prompts the technician to enter his or her identification code. At step 394, IM 18 verifies the entered code against the database of qualified technicians. If, at step 396, IM 18 determines that the technician is not qualified it notifies the network of the unqualified technician status and returns to step 392 which repeats the above process until a valid technician ID is entered. At step 398, once a valid technician has been located, the technician is prompted to enter the cover seal lot number. At step 400, IM 18 polls network 24 to determine the validity of this lot number. If, at step 402, the lot number is invalid IM 18 displays a message to that effect and returns control to step 398 to request the technician to enter another cover seal and lot number. If at step 403, the lot number is found to be valid, then IM 18 causes the lot number to be entered into the network library for use by system 10. At step 404, the COVER SEAL LOT NUMBER

ENTRY routine returns control to the MONITOR AND FUNCTION ENTRY routine, described above with reference to figure 12.

Figure 20a describes the program flow for the BEAD ADDITION routine. At the first step of this routine, step 406, the technician is prompted to enter his identification code. At step 408 IM 18 verifies that the Identification code is valid against the network database of qualified technicians. At step 410, if it was determined that the technician is not qualified, IM 18 notifies network 24 of the unqualified technician status and returns to step 406 until a valid technician identification code is entered.

At step 412, once a valid technician identification code has been entered, the technician is prompted to wand the Identification code number into IM 18 from the tray. At step 414, IM 18 requests from network 24, the processing protocol to be used for this tray. At step 416, the IM 18 verifies that the tray is ready for bead addition based on the received protocol sequence. Next, at step 418, if the IM 18 determines that the tray is out of sequence, and therefore not ready for bead addition, it notifies the technician as to where the tray should be in the system and transfers control to the MONITOR AND FUNCTION ENTRY routine.

Otherwise, if the tray is ready for bead addition, the technician is prompted to enter the bead lot number at step 420. After the technician has entered the lot number, IM 18 polls network 24, at step 422, to

determine the validity of the lot number. If IM 18 determines that the lot number is invalid, then, at step 424, it displays a message to that effect and returns control to step 420 until a valid lot number is entered. At step 426, once a valid lot number has been entered, it is recorded and displayed by IM 18.

At step 436, IM 18 displays a message requesting the operator to dispense the beads, verify that the beads have been dispensed, tap the tray, cover the tray and press "done" when the tray has been covered. Next, at step 437, the technician (operator) is prompted to verify the lot number against the display which shows the current library lot number. If the lot number of the cover seal is not the one displayed, the technician may enter a new lot number into the library. At step 438 in the process, the technician dispenses the beads into the tray, visually inspects the tray and taps the tray to settle the beads. At step 440, the technician places the cover seal on the tray. At step 442, when the technician has pressed the "done" key on IM 18, IM 18 stores the time the beads were dropped and stores the cover seal lot number information. At step 444, IM 18 notifies network 24 of the time the beads were dropped and the cover seal lot number. At step 446, the BEAD ADDITION routine transfers control the BEGIN INCUBATION routine, described above with reference to figures 13a and 13b.

Figure 21a and 21b show the program flows for the CONJUGATE RECONSTITUTION routine. This routine starts at step 448 when IM 18 prompts the technician to enter his identification code. At step 450, IM 18 verifies the technician identification code against network 24 database of qualified technicians. If, at step 452, IM 18 determines its technician is not qualified, it notifies network 24 of the unqualified technician status and returns control to step 448 until a valid technician identification code is entered.

At step 454, the technician is prompted by IM 18 to wand the identification information from the conjugate concentrate and conjugate diluent containers. At step 456, IM 18 receives this identification information and polls network 24 for its validity. Network 24 responds with the validity data at step 458. If, at step 460, IM 18 was informed by network 24 that the conjugate diluent or conjugate concentrate were invalid, it displays an error message and returns to step 454 until information from valid containers is entered. At step 462, when valid containers are available, the technician is prompted to combine the concentrate and conjugate diluent.

Next, at step 464, the technician defaces and relabels the bottle containing the diluted concentrate. At step 466, a new conjugate bar code is placed on the bottle containing the diluted concentrate. At step 468, the technician is prompted to wand the new conjugate bar code. IM 18 receives this information and passes it on to network 24.

Network 24 responds at step 470 by providing a time and date at which the conjugate was reconstituted and an expiration time and date. At step 472, IM 18 stores the conjugate lot number and expiration time and date, the diluent lot number and expiration time and date, the time and date at which the reconstitution was started, and the lot number and expiration time and date for the diluted conjugate. At step 474, IM 18 passes this information on to network 24.

Next, at step 476, the technician is prompted to add the displayed information to the label on the bottle that holds the reconstituted conjugate. At step 478, IM 18 starts a 30-minute timer. This timer defines a time in which the conjugate is allowed to stabilize before it may be used. At step 480, when the 30-minute timer expires, IM 18 stores the time and date at which the reconstitution was completed. At step 482, IM 18 notifies network 24 of this time and date. In the exemplary system, network 24 will not allow the diluted conjugate to be used before the 30-minute timer has elapsed or after its expiration time and date. At step 486, the final step of the CONJUGATE RECONSTITUTION routine, control is transferred back to the MONITOR AND FUNCTION ENTRY routine.

Figures 22a and 22b describe the program flow for the OPD PREPARATION routine. This routine is very similar in its operation to the CONJUGATE RECONSTITUTION routine, described above with reference to Figures 21a and 21b.

At the first step of the OPD PREPARATION routine, step 488, IM 18 prompts the technician to enter his identification code. At step 490, IM 18 verifies the entered identification code against network 24 database of qualified technicians. If, at step 492, IM 18 determines that the entered technician identification code is not valid or that the technician is not qualified, it notifies network 24 of unqualified technician status and returns control to step 488 until the identification code of a qualified technician is entered.

At step 494, IM 18 prompts the technician to wand the identification information from the OPD tablet container and the diluent container. At step 496, IM 18 passes this information on to network 24 to determine the validity of the tablets and diluent. At step 498, network 24 responds with this validity information. If, at step 500, IM 18 is informed that the OPD tablets or the diluent is invalid, it displays an error message and returns control to step 494 until information from valid containers is entered.

At step 502, the OPD tablets and diluent are valid and the technician is prompted to combine the tablets with the diluent. At step 504, the technician is prompted to deface and relabel the bottle which holds the OPD substrate (which is a combination of tablets and diluent), and at step 506, to add a new OPD substrate bar code. At step 508, the technician wands the new substrate bar code into IM 18 which passes it on to network 24. Next, at step 510, network 24 responds by sending the date and time at

which the OPD was prepared and an expiration date and time for the OPD solution to IM 18.

The next step in the process is step 512 of Figure 22b. At this step, IM 18 stores the OPD lot number, expiration time and date, diluent lot number with its expiration time and date, the time and date at which the reconstitution was started, lot number of the prepared OPD substrate and its expiration date. At step 514, IM 18 passes this information on to network 24.

At step 516, the technician is prompted to add this information to the OPD substrate label. Next, at step 518, IM 18 starts a 30-minute timer to allow the newly prepared OPD solution to stabilize. At step 520, when the timer expires, IM 18 stores the time and date at which the reconstitution was completed. Next, at step 522, IM 18 notifies network 24 of the time and date at which the OPD reconstitution was completed. At step 526, the last step of the OPD PREPARATION routine, control is returned to the monitor and function entry routine described above with reference to Figures 12a and 12b. System 10, through network 24 database, will not allow the OPD substrate to be used during the 30-minute stabilization period or after its expiration time and date.

Figure 23 is a flow chart diagram which illustrates an exemplary test which may be performed using the system shown in Figure 1.

In the first step of this test, step 570, the reagents are prepared. In the exemplary test three reagents are used, a conjugate, OPD and an acid. Depending on the status of system 10, these reagents may be already available at room temperature in which case step 570 simply consists of attaching an external pump device to each of the bottles. If the reagents are prepared but stored in the cooler, they must be removed and allowed to stand at room temperature for 30 minutes or some other appropriate time, before they may be used. This process is described above with reference to Figure 18.

If no reagents are available at room temperature and none are in a prepared state and stored in the cooler, then reagents must be prepared; conjugate from concentrate and OPD from OPD tablets. The processes for preparing each of these reagents are described above with reference to Figures 21A and 21B for the conjugate, and with reference to Figures 22A and 22B for the OPD.

The end result of step 570, which is described below in greater detail with reference to FIG. 24, is a supply of three reagents, a conjugate, an OPD solution and an acid.

With the reagents available and at room temperature, the next step in the process, step 572, is to process a tray of samples through a processing unit 16 using the conjugate. The steps for processing each tray using a reagents are described below with reference to Figures 25, 26 and 27A and 27B.

Once the tray samples has been processed using the conjugate at step 572, the next step, 574 processes the tray through bead addition and incubation stages. In the exemplary embodiment of the invention both of these processing stages are performed on Incubator Monitor 18, and are described above with reference to Figures 20A and 20B for the bead addition and Figures 13A, 13B, 14A and 14B for the incubation.

The next step in the process shown in Figure 23, step 576, processes the tray of samples using the OPD solution as the reagent. As with step 572, the steps performed by Processing Center 16 to implement step 576, are described below with reference to Figures 25, 26, 27A and 27B.

After the tray has been processed to Processing Center 16 using the OPD, the next step in the process is an OPD incubation performed at step 578. The incubation step is performed at Incubator Monitor 18, and Incubators 20 or 21 as described above with reference to Figures 13A, 13B, 14A and 14B.

When the tray has been removed from the incubator after its OPD incubation, it is processed again though Processing Center 16 using the acid as the reagent. This is illustrated by step 580 and described below with reference to Figures 25, 26, 27A and 27B.

At the end of processing the tray, using the acid as the reagent, the processing center 16 reads the

results of the test at step 582. The manner in which the test described above with reference to Figure 23 is implemented is described below in greater detail with reference to Figure 31.

Figure 24 is a program flow diagram which illustrates the PREPARE REAGENTS routine shown in Figure 23. This routine assumes that prepared reagents are available in a cooler (now shown). The next step in this routine, step 586 is to bring the reagents to the work station and, at step 588, to allow the reagents to come to room temperature for 30 minutes. In the exemplary embodiment of the invention these two steps are performed using the incubator monitor 18, and are described above with reference to Figure 18.

The next step in the process shown in Figure 24, is to put the TRI-CONT onto each of reagent bottles. In the exemplary embodiment of the invention, the TRI-CONT is a small external pump mechanism which is attached to each of the reagent bottles, so that, when the bottles are fitted into a Processing Center 16, Processing Center 16 will be able to dispense the reagent from the bottles. Step 592 completes the prepare reagents routine by priming each of the TRI-CONTS to make them ready for use by their Processing Centers 16.

Figure 25 is a program flow diagram which illustrates the operation of a valid tray routine which is one of the routines run to process a tray through one of the Processing Centers 16. At the first step of this

routine, step 594, Processing Center 16 prompts the operator to put the tray into Processing Center 16 entrance chute. At step 596, Processing Center reads the tray bar code or requests keyboard entry of the bar code by the technician. Next, at step 598, Processing Center 16 determines if the tray is active and has valid control samples. At step 600, if Processing Center 16 receives information from network 24 indicating that the tray is invalid, it displays an appropriate message and instructions to the operator and returns to step 594 to wait until a valid tray is entered.

Figure 26 is a program flow diagram which illustrates the operation of the VALID TECHNICIAN routine. This is a second routine run in processing the trays as in steps 572, 576 and 580 of Figure 23. At the first step of this routine, step 602, Processing Center 16 displays a message asking the technician to enter his ID code. At step 603 the operator enters his ID code and at step 604 Processing Center 16 polls the system by network 24 to determine if the technician ID is valid. At step 605, if the technician ID is found not to be valid the processing center displays an appropriate error message and instructions and returns control to step 602 until a proper technician ID is entered.

Figures 27A and 27B are flow diagrams which illustrate the bulk of the processing performed by Processing Center 16 in processing a tray with one of the reagents (i.e. the conjugate solution, the OPD solution or the acid). At the first step in this process, Processing

Center 16 displays a message asking the operator to enter the number of trays in the batch. At step 608, the operator enters the number of trays. At step 610, Processing Center 16 displays the assay name and number reagent location and asks the operator to enter the reagent identification information from the bar code on the reagent bottle. At step 612, the operator enters the reagent information using, for example, bar code reader 19. Alternatively, the operator may use a dedicated bar code reader (not shown), coupled to Processing Center 16.

Upon receiving the reagent identification information, at step 614, Processing Center 16 polls system 10 through network 24 to determine if the reagent is valid. At step 616, Processing Center receives a message from network 24 indicating the status of the reagent.

If, at step 618, the reagent is invalid, Processing Center 16 displays an appropriate message and loops back to step 610 until a valid reagent lot number is entered.

At the next step of the process, step 620, Processing Center 16 displays a message asking the operator to enter the volume of the reagent. At 622, the operator reads the approximate volume from the reagent bottle using demarcations on the bottle. At step 624 the operator enters this volume via the keyboard (now shown) coupled to Processing Center 16. Next, at 626, Processing Center 16 displays a number of samples and controls which can be processed and requests entry ("yes" or "no") if the number

of samples and controls in the batch is less than or equal to the number that is displayed. At step 628, if the answer entered by the operator is "no", Processing Center 16 displays an appropriate message and loops back to step 620 until the operator enters an volume which is suitable for the number of samples.

The next step in the process is step 630 of Figure 27B. At this step Processing Center 16 displays a message asking the operator to load the reagent on a particular station number and enter the reagent station number. At step 632, the operator loads the reagent into the displayed station including tubing and tip necessary to dispense the reagent. At step 634, the operator enters the station number via the bar code reader 19 or the bar code reader (not shown) next to the station, or alternatively by the keyboard (not shown) coupled to Processing Center 16. Next, at step 636, Processing Center 16 displays the message "valid station." At step 638, the operator enters "yes" or "no" to verify that the station is valid. At step 640, if the operator answered "no" to the valid station request, Processing Center 16 displays an appropriate message and loops back to step 630 until the reagent container is loaded into a valid station. At step 642, Processing Center 16 displays the message "insert tray." At step 644, Processing Center 16 displays a message "ready." At step 646, the operator enters either "yes" or "no" to approve processing. If, at step 648, the operator has entered a "no", Processing Center 16 displays an appropriate message to remove the tray.

At step 650, once the reagent is loaded, Processing Center 16 pulls the tray in to dispense the reagent. At step 652, Processing Center 16 saves the time when the processing begins. At step 654 Processing Center 16 completes processing and at step 656, passes the tray to the exit chute after the reagent has been dispensed. Next, at step 658, Processing Center 16 sends a processing complete message, the dispense start time and stop time, and any error conditions which were encountered and any voided wells to the Data Management System 12 via network 24. At step 660, Processing Center 16 emits a beep to signal the operator that it is time to remove the tray from the exit chute if necessary. At step 662, the operator removes the tray from the exit chute.

When the assay requirements as defined by the assay protocol or "recipe" have been completed, the results will be collated by DMS 12. Figure 28, step 670 describes accepting these results. The technician may choose to either accept the batch results or not. If the results are accepted, then at step 672 the results go through the decision making tables stored in the database of DMS 12. At step 674, the technician may then designate whether the results are to be used in statistical reports. This allows the user to screen invalid or erroneous runs out of reports used for analysis.

Subsequent to running various tests on various samples, the user has options to generate reports. Figure 29 describes some of these options. Operational reports include batch reports on current sample results such as

those described at step 676. Step 678 describes an exception report, that is, a list of all unacceptable sample results. Step 680 describes the retest report which details those samples requiring further iterations of tests based on statistical accuracy measurements. Step 682 describes typical Quarantine Reports which will provide the user a list of sample identification numbers for those samples reactive to a particular test.

The user may use this report to quarantine materials associated with the biological material being tested. Management or decision support reports typically include comprehensive batch records and statistical reports such as described in figure 30. Step 684 describes a batch record which will include a history of all results, decisions, processing steps, reagents and commodities used (i.e. lot number, expiration date), technicians performing steps, instruments used for processing, times processing took place, and other parameters. Step 686 describes statistical reports which will be defined by the user. Examples may include reports describing control performance, reagent performance, incidence of reactive results and the like.

All of this information (data) can be stored in a long-term storage device (not shown) on or off network 24 for later retrieval.

There is shown in Figure 23 a flow diagram for the operation of the method of the present invention. There is shown in block 550 the step of identifying the

sample to be tested. In the exemplary embodiment, this involves scanning the bar code on the test tube containing the sample to be tested. In block 552, the identification information of the sample read in block 550 is communicated to the storage device and database which contains the information regarding the test(s) to be undertaken for the particular sample. This information will be communicated back to Pipettor 14 or FPC, along network 24 to pipet the proper aliquot to the proper test sites.

In block 54, the particular test site is identified. The identification is completed by scanning the bar code on the test tray containing the test sites. The test sites are set up as a matrix with their own particular identification and database coordinated to the bar code label identifying the test tray. In block 556 the identification information for the test site (test tray) is communicated over network 24 to the storage device and database containing this information. It is possible that this information is stored locally at a pipettor 14 or at a pipettor monitor 13. The feature of the storage is that the information is accessible to the pipettor and any other device which may require access to this information.

In block 558, the aliquot of sample is delivered to the appropriate test site, depending upon the test required for the sample. This information is provided by DMS 12 along network 24 to pipettor 14 (or pipettor monitor 13).

In block 560, the aliquot of sample is tested. This testing may involve reagent addition through a proccessing center 16 and/or incubation in an incubator 20. Further, testing may involve the addition of a coated bead or similar reagent delivery method. Further, testing may involve multiple passes through processing center 16 and/or incubation in an incubator 20. The exact test steps depend upon the test being conducted on the particular aliquot of sample. In block 562, results of the tests are read. In the exemplary embodiment, 16 is capable of reading the test result(s) by spectraphotometric variation of the test sample during the test process. Finally, in block 564 the test results are communicated to a memory storage device such as DMS 12 for later retrieval by the user of the system.

The present invention has been described in terms of exemplary embodiments. It is contemplated, however, that it may be practiced with modifications, some of which are outlined above, within the scope of the appended claims.

The Invention Claimed is:

1. A system suitable for use in testing biological fluids, comprising:

a data communications network;

means for receiving a sample of a biological fluid having an identifying label and for communicating identifying information contained on the label to the network;

means, coupled to the data communications network, for receiving the identifying information to determine at least one test to be performed on the sample;

means, coupled to the data communications network, for testing the sample according to the determined test and for communicating results of the test to the network; and

means for receiving and recording the results of the test from the network.

2. A system for testing a sample of a biological fluid comprising:

pipetting means for transferring a portion of the sample to a test site;

reagent testing means for applying at least one reagent to the test site;

means for incubating the test site, treated by the reagent testing means;

a network which is coupled to provide data communications among the pipetting means, the reagent testing means and the means for incubating; and

a data processing system, coupled to the network, for coordinating and tracking operations performed in the testing system by providing commands to and receiving data from each of the pipetting means, the reagent testing means and the means for incubating, via the network.

3. A method for testing biological fluids comprising the steps of:

identifying a sample of a biological fluid for testing;

communicating identification information of said sample to a first memory storage location on said communication network;

identifying a test site;

communicating identification information of said test site to a second memory storage location on said communication network;

delivering a predetermined amount of said sample to a test site;

testing said sample;

reading a result of said test;

communicating said result to a third memory storage device, said third memory storage location on said communication network.

4. The method of claim 3 wherein said step of testing said sample further comprises the steps of:

transporting said test site to a test device;

identifying said test site at said test device;

communicating identification information of said test site at said test device to a fourth memory storage device, said fourth memory storage location on said communication network;

communicating testing instructions to said test device over said communication network;

adding reagents to said test site, according to said testing instructions.

5. The method of claim 4 further comprising the steps of:

transporting said test site to an incubator;

identifying said test site at said incubator;

communicating identification information of said test site at said incubator to a fifth memory storage location, on said communication network;

communicating incubation instructions for said sample to said incubator over said communication network;

incubating said sample in said incubator according to said incubation instructions.

6. The method of claim 5 further comprising the steps of:

entering reagent information of reagents into a memory storage device;

identifying said reagents to be loaded onto said test device;

loading said reagents onto said test device;

reading said reagent information prior to conducting a test; and

determining whether said reagents are adequate for conducting said test.

7. A method for testing biological fluids comprising the steps of:

identifying a sample of a biological fluid for testing;

communicating identification information of said sample to a memory storage location, on a communication network;

identifying a test site;

communicating identification information of said test site to said memory storage location;

communicating delivery information for said sample to a delivery device over said communication network;

delivering said sample to said test site according to said delivery information;

transporting said test site to a reagent testing device;

identifying said test site at said reagent testing device;

communicating identification information of said test site at said testing device to said memory storage location;

communicating test information to said testing device over said communication network;

applying reagents to said test site according to said testing information;

transporting said test site to an incubation device;

identifying said test site at said incubation device;

communicating identification information of said test site at said incubation device to said memory storage location; and

communicating incubation initiation instructions to said incubation device over said communication network.

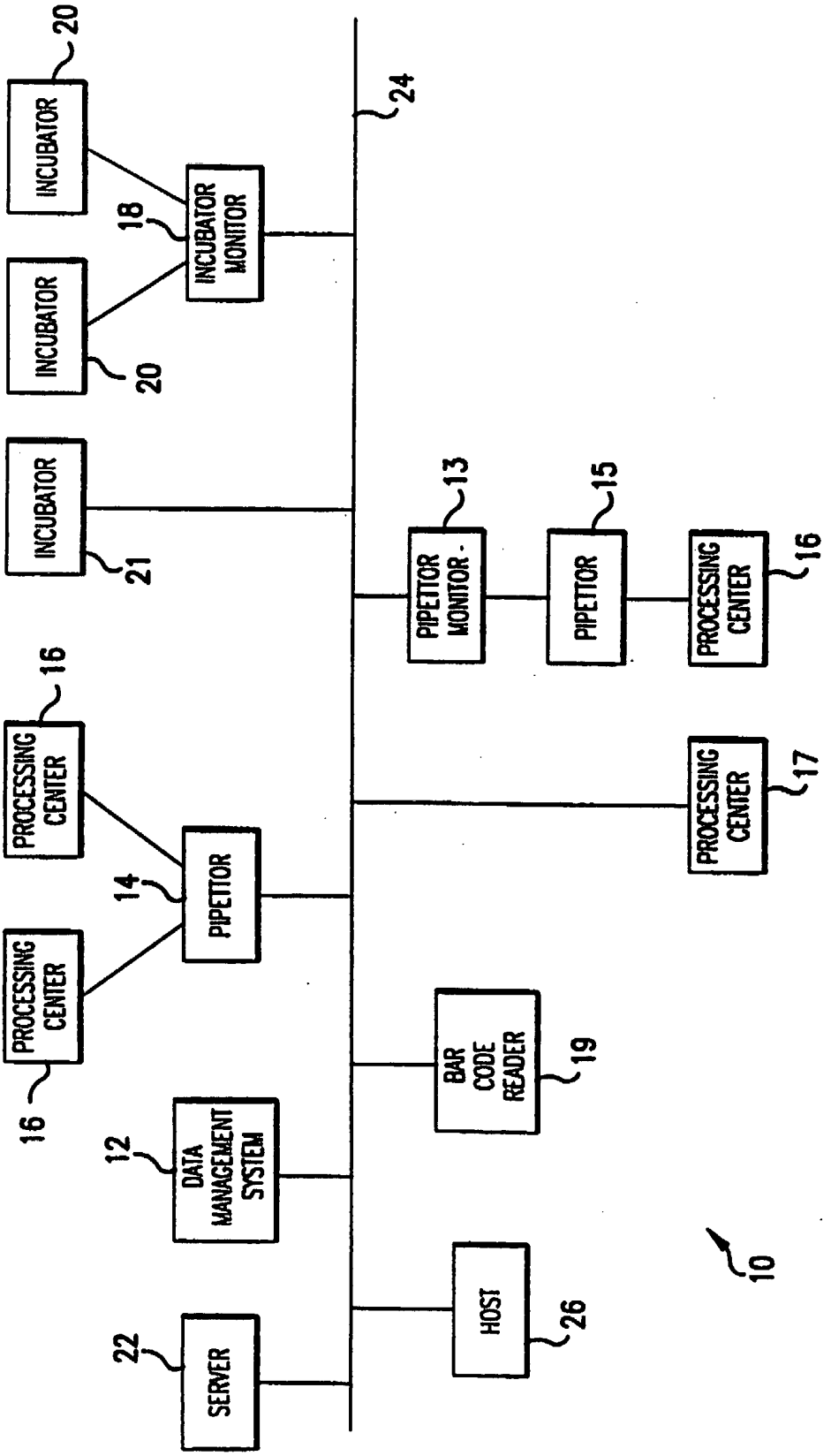
INCUBATOR
20
INCUBATOR MONITOR
18
INCUBATOR
20
INCUBATOR
21
24
PIPETTOR MONITOR
13
PIPETTOR
15
PROCESSING CENTER
16
PROCESSING CENTER
16
PROCESSING CENTER
17
PIPETTOR
14
PROCESSING CENTER
16
BAR CODE READER
19
DATA MANAGEMENT SYSTEM
12
SERVER
22
HOST
26
10

FIG. 1

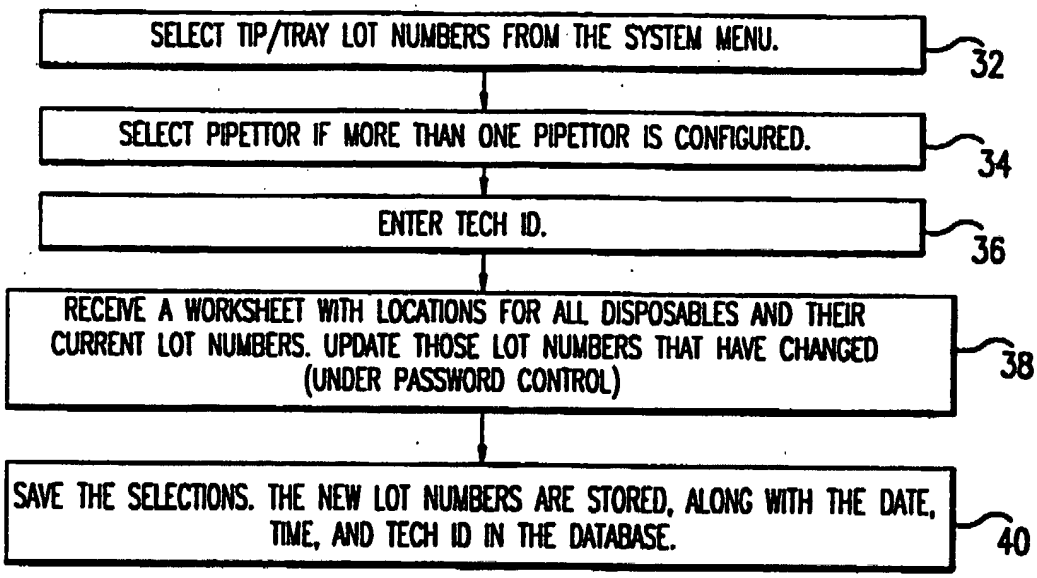

FIG.2

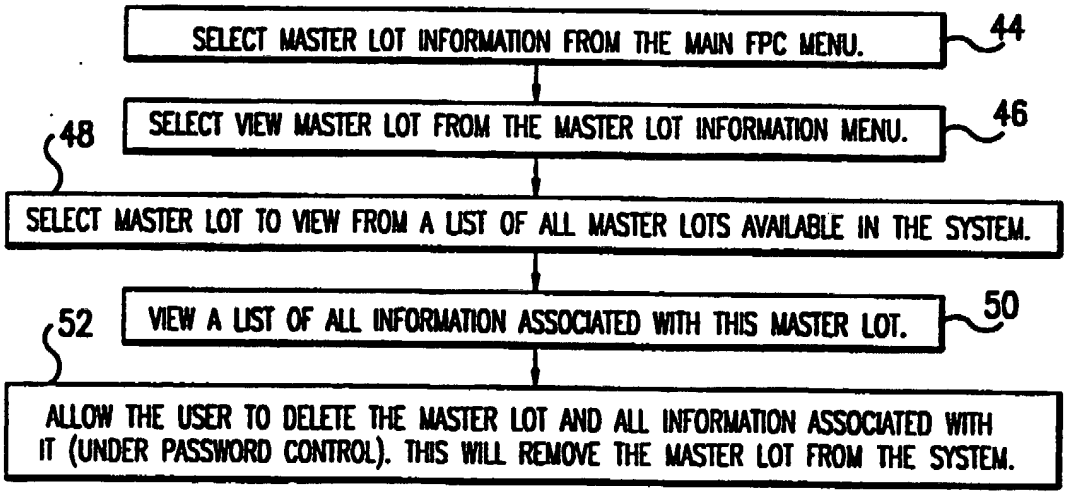

FIG.3

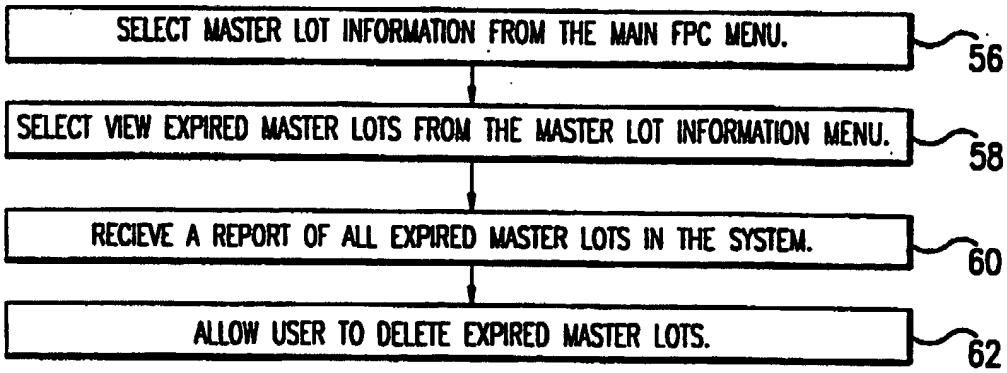

FIG.4

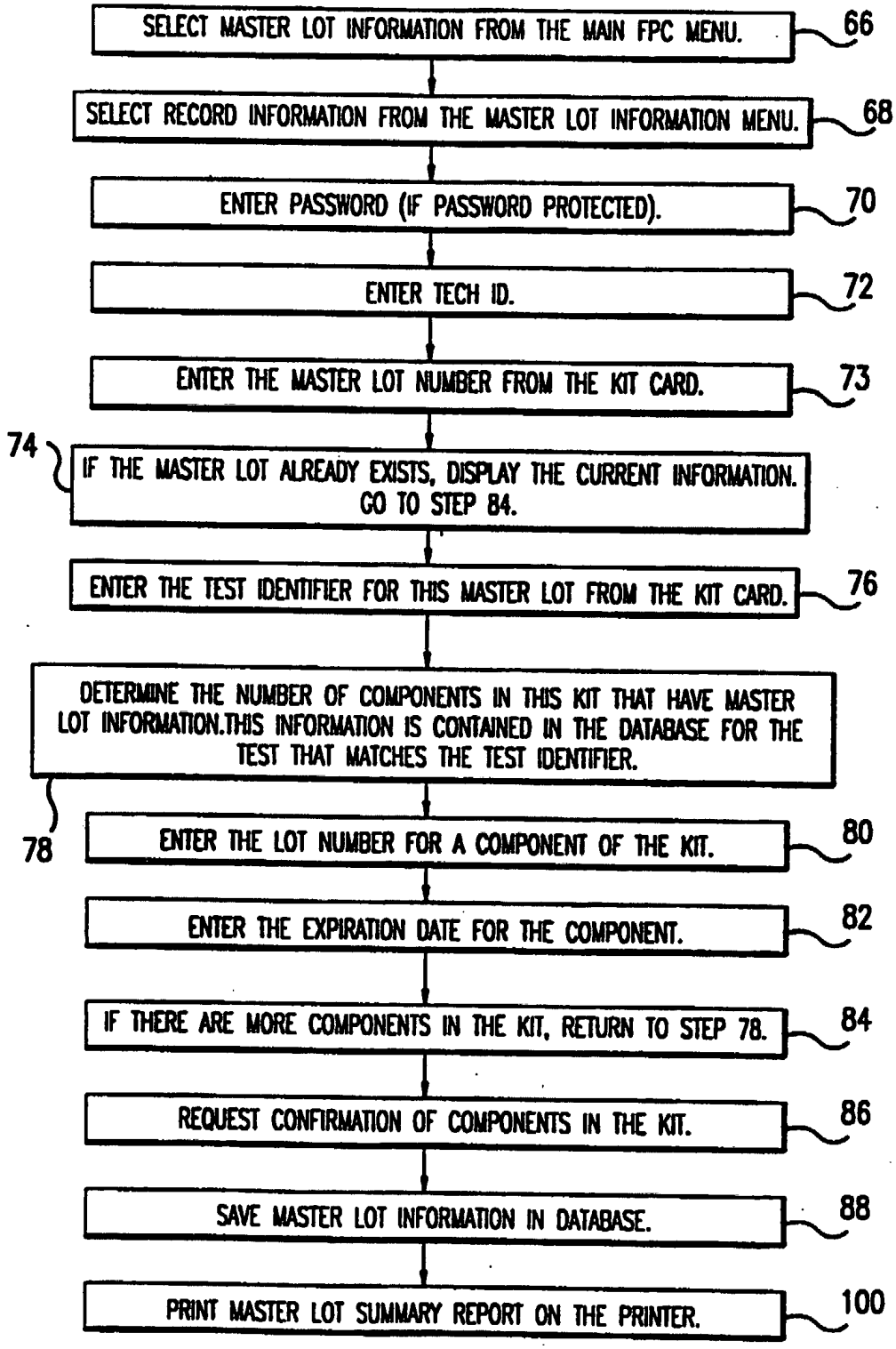
SELECT MASTER LOT INFORMATION FROM THE MAIN FPC MENU.
66
SELECT RECORD INFORMATION FROM THE MASTER LOT INFORMATION MENU.
68
ENTER PASSWORD (IF PASSWORD PROTECTED).
70
ENTER TECH ID.
72
ENTER THE MASTER LOT NUMBER FROM THE KIT CARD.
73
74
IF THE MASTER LOT ALREADY EXISTS, DISPLAY THE CURRENT INFORMATION. GO TO STEP 84.
ENTER THE TEST IDENTIFIER FOR THIS MASTER LOT FROM THE KIT CARD.
76
DETERMINE THE NUMBER OF COMPONENTS IN THIS KIT THAT HAVE MASTER LOT INFORMATION.THIS INFORMATION IS CONTAINED IN THE DATABASE FOR THE TEST THAT MATCHES THE TEST IDENTIFIER.
78
ENTER THE LOT NUMBER FOR A COMPONENT OF THE KIT.
80
ENTER THE EXPIRATION DATE FOR THE COMPONENT.
82
IF THERE ARE MORE COMPONENTS IN THE KIT, RETURN TO STEP 78.
84
REQUEST CONFIRMATION OF COMPONENTS IN THE KIT.
86
SAVE MASTER LOT INFORMATION IN DATABASE.
88
PRINT MASTER LOT SUMMARY REPORT ON THE PRINTER.
100

FIG.5

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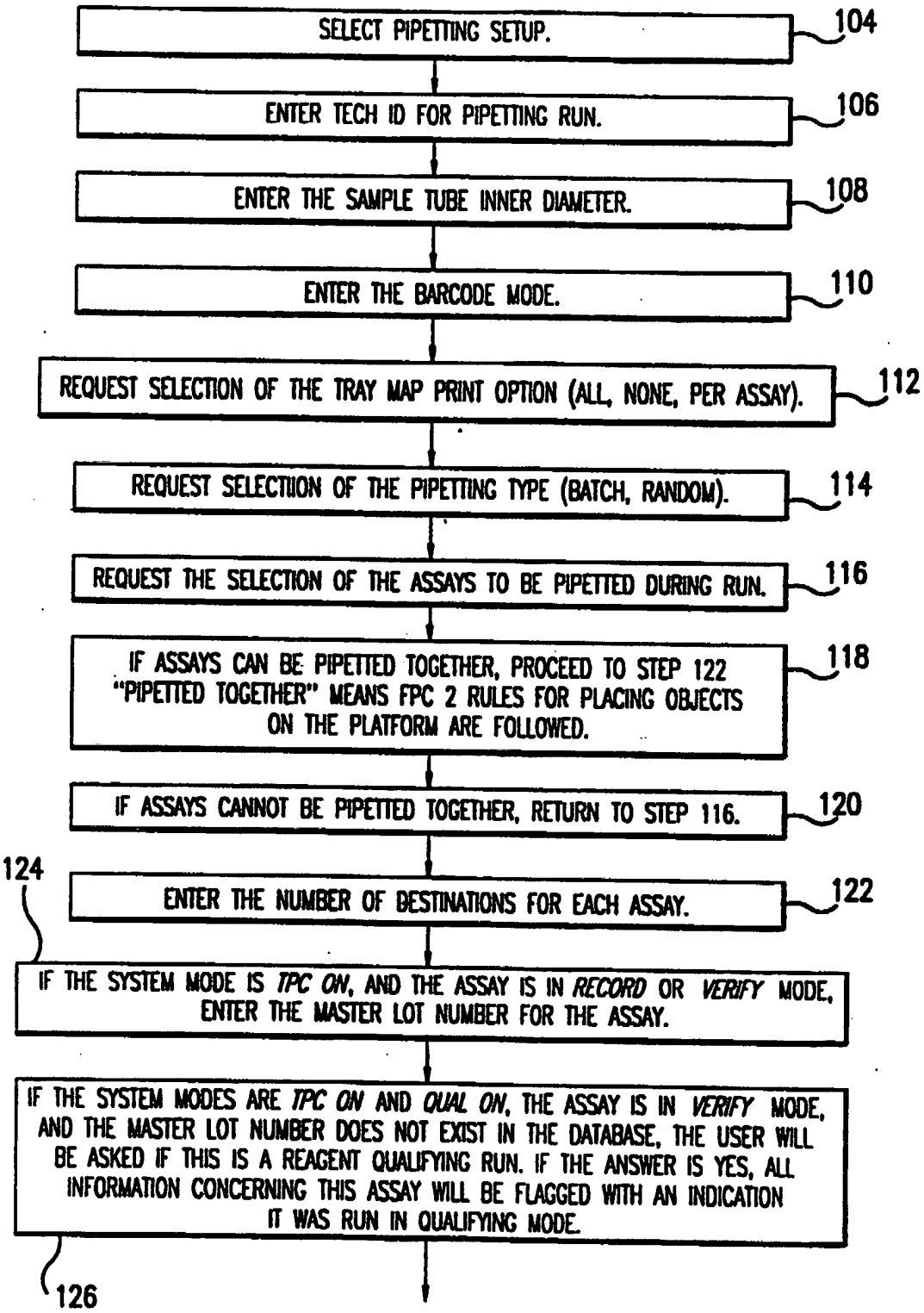
SELECT PIPETTING SETUP.
104
ENTER TECH ID FOR PIPETTING RUN.
106
ENTER THE SAMPLE TUBE INNER DIAMETER.
108
ENTER THE BARCODE MODE.
110
REQUEST SELECTION OF THE TRAY MAP PRINT OPTION (ALL, NONE, PER ASSAY).
112
REQUEST SELECTIION OF THE PIPETTING TYPE (BATCH, RANDOM).
114
REQUEST THE SELECTION OF THE ASSAYS TO BE PIPETTED DURING RUN.
116
IF ASSAYS CAN BE PIPETTED TOGETHER, PROCEED TO STEP 122
"PIPETTED TOGETHER" MEANS FPC 2 RULES FOR PLACING OBJECTS
ON THE PLATFORM ARE FOLLOWED.
118
IF ASSAYS CANNOT BE PIPETTED TOGETHER, RETURN TO STEP 116.
120
124
ENTER THE NUMBER OF DESTINATIONS FOR EACH ASSAY.
122
IF THE SYSTEM MODE IS TPC ON, AND THE ASSAY IS IN RECORD OR VERIFY MODE,
ENTER THE MASTER LOT NUMBER FOR THE ASSAY.
IF THE SYSTEM MODES ARE TPC ON AND QUAL ON, THE ASSAY IS IN VERIFY MODE,
AND THE MASTER LOT NUMBER DOES NOT EXIST IN THE DATABASE, THE USER WILL
BE ASKED IF THIS IS A REAGENT QUALIFYING RUN. IF THE ANSWER IS YES, ALL
INFORMATION CONCERNING THIS ASSAY WILL BE FLAGGED WITH AN INDICATION
IT WAS RUN IN QUALIFYING MODE.
126

FIG.6

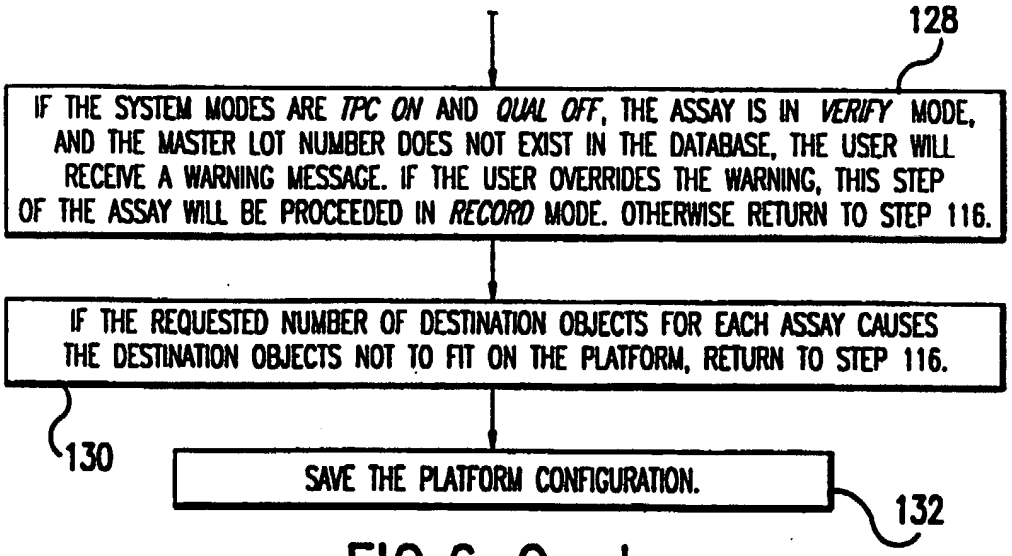

FIG.6 Cont.

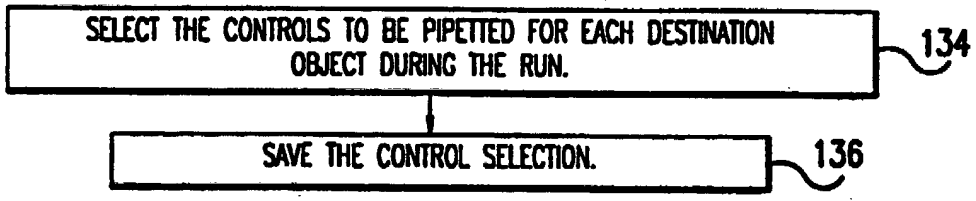

FIG.7

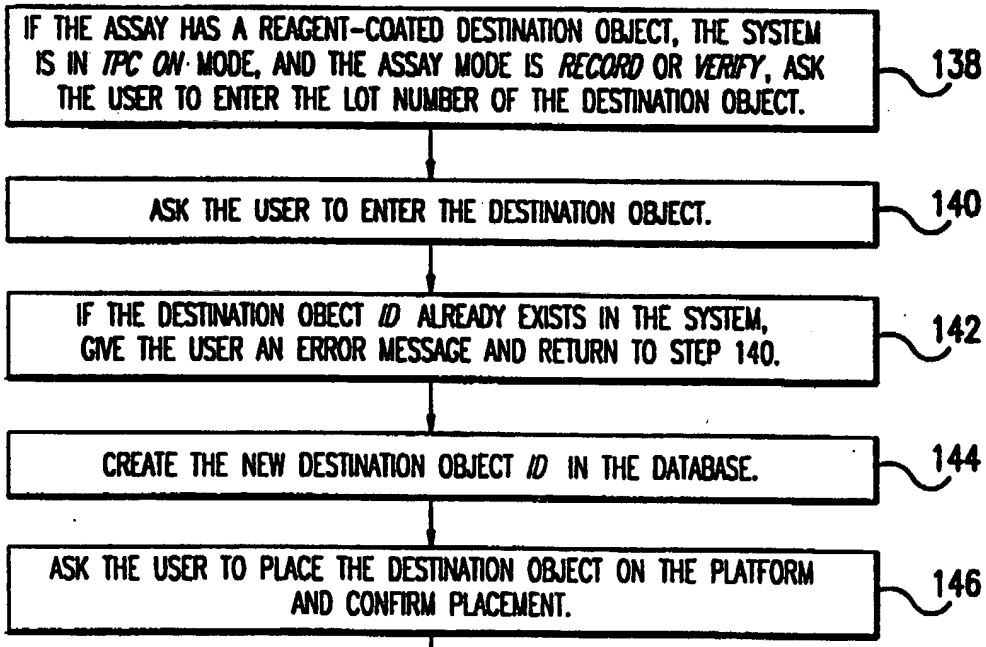

FIG.8

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IF THERE ARE MORE DESTINATION OBJECTS THAT NEED TO BE PLACED, RETURN TO STEP 138. OTHERWISE, CONTINUE WITH STEP 138. 148

FIG.8 Cont.

DISPLAY A SCREEN INDICATING THE LOCATION FOR ALL REAGENTS AND CONTROLS ON THE PLATFORM. 150

IF THE SYSTEM MODE IS *TPC ON*, AND THE ASSAY MODE IS *RECORD* OR *VERIFY* MODE, REQUEST A LOT NUMBER FOR THE DILUENT OR CONTROL BOTTLE. TO OVERRIDE *RECORD* MODE, THE USER PRESSES <ENTER>. TO OVERRIDE *VERIFY* MODE, THE USER MUST CONFIRM A WARNING MESSAGE.

152 CHECK THE *ID* OF THE CONTROL AGAINST THE MASTER LOT LIST (*TPC ON* AND *VERIFY* MODE ONLY). 154

IF THE *ID* DOES NOT MATCH AN ENTRY IN THE LIST, GIVE THE USER AN ERROR MESSAGE AND RETURN TO STEP 152 (*TPC ON* AND *VERIFY* MODE ONLY) 156

IF THE EXPIRATION DATE OF THE CONTROL HAS BEEN REACHED, GIVE THE USER AN ERROR MESSAGE AND GO TO STEP 168 (*TPC ON* AND *VERIFY* MODE ONLY) 158

IF THE MASTER LOT CONTROL IS NOT CONSISTENT WITH THE OTHER CONTROLS IN USE FOR THIS ASSAY, GIVE THE USER AN ERROR MESSAGE AND GO TO STEP 168 (*TPC ON* AND *VERIFY* MODE ONLY) 160

ASK THE USER TO PLACE THE CONTROL BOTTLE IN THE SELECTED POSITION. 162

ASK THE USER TO BARCODE THE POSITION OF THE CONTROL BOTTLE. IF THE POSITION DIFFERS FROM THE EXPECTED POSITION, GIVE THE USER AN ERROR MESSAGE AND RETURN TO THIS STEP. 164

CONTINUE WITH STEP 152 FOR ALL REMAINING DILUENTS AND CONTROLS FOR THIS PIPETTOR RUN. IF ALL DILUENTS AND CONTROLS HAVE BEEN ASSIGNED POSITIONS, GO TO STEP 174. 166

FIG.9

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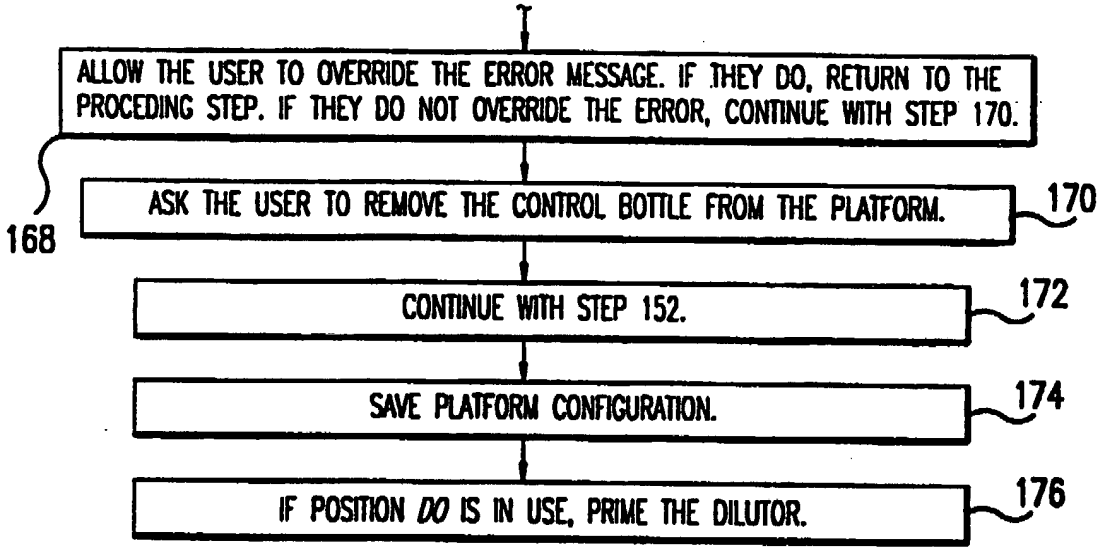

FIG.9 Cont.

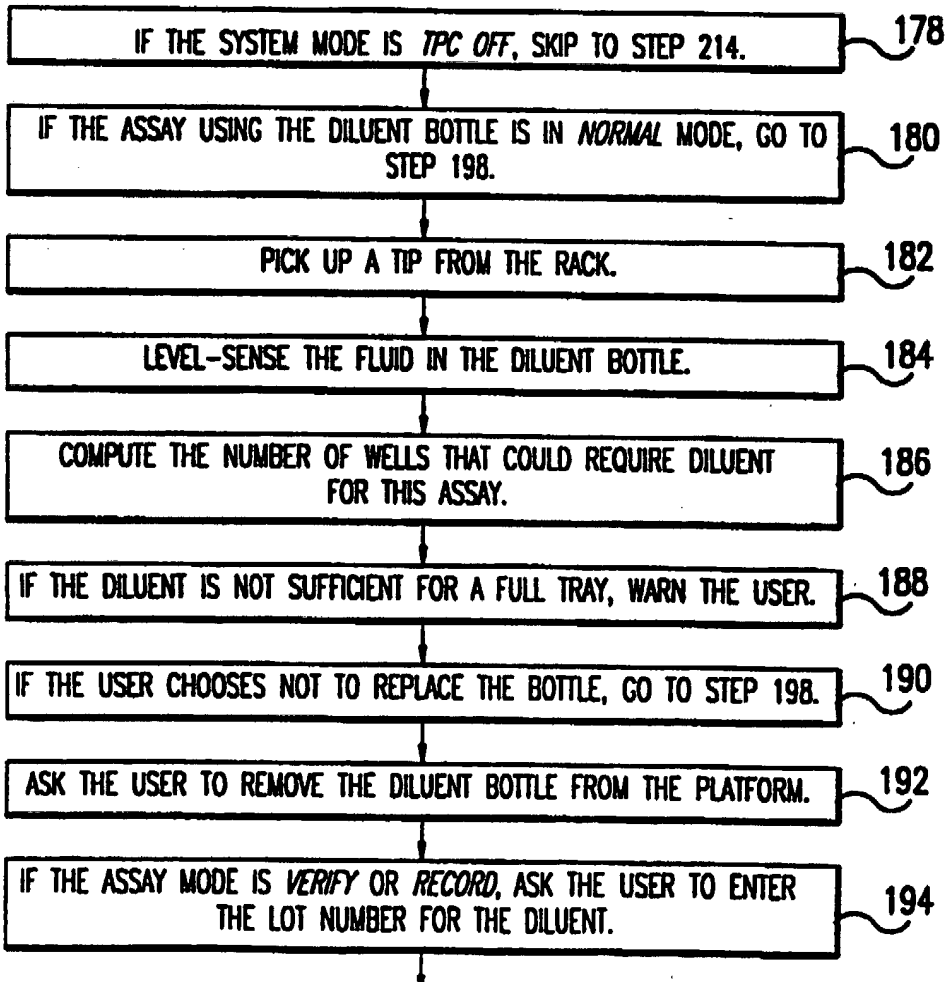

FIG.10

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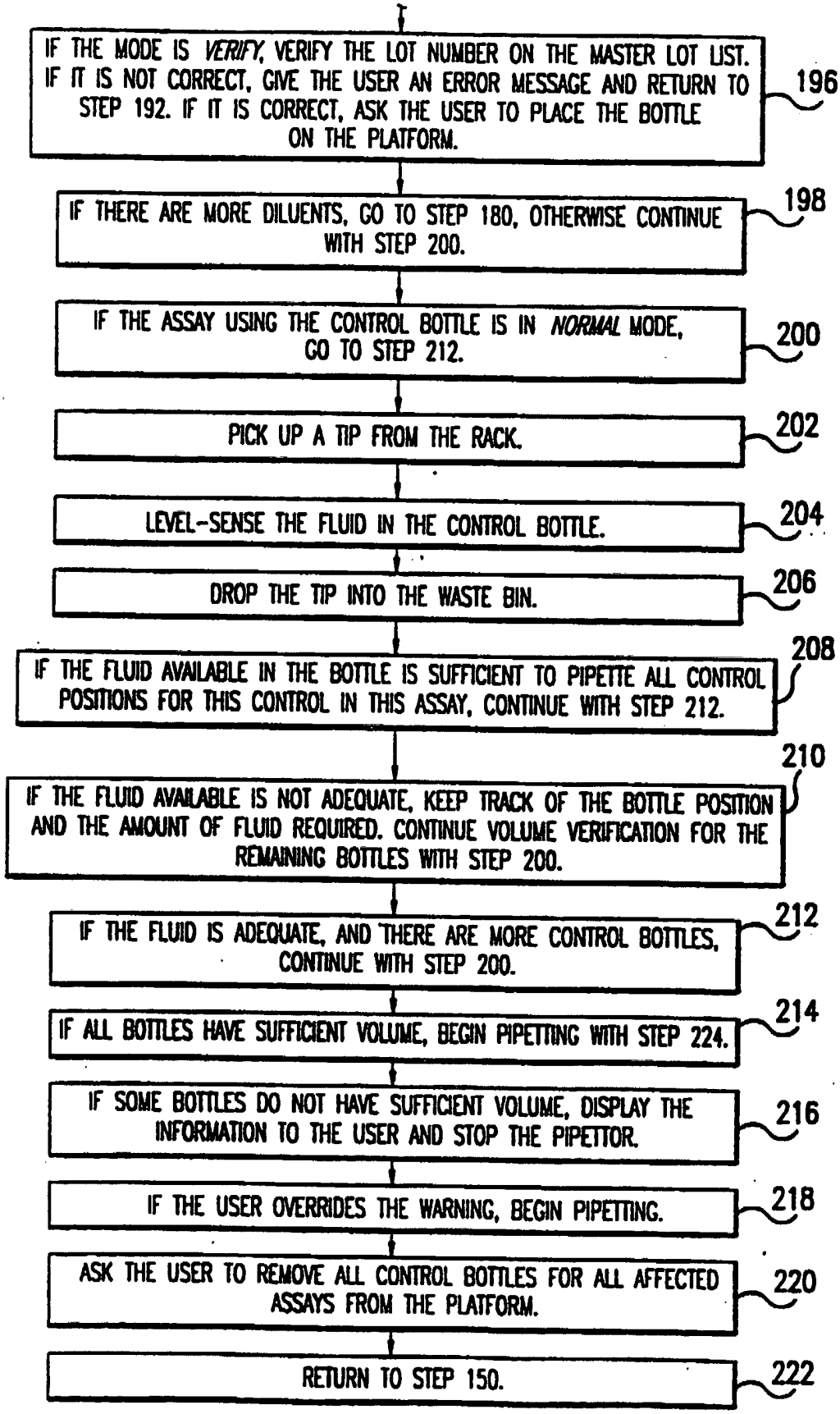

FIG.10 Cont.

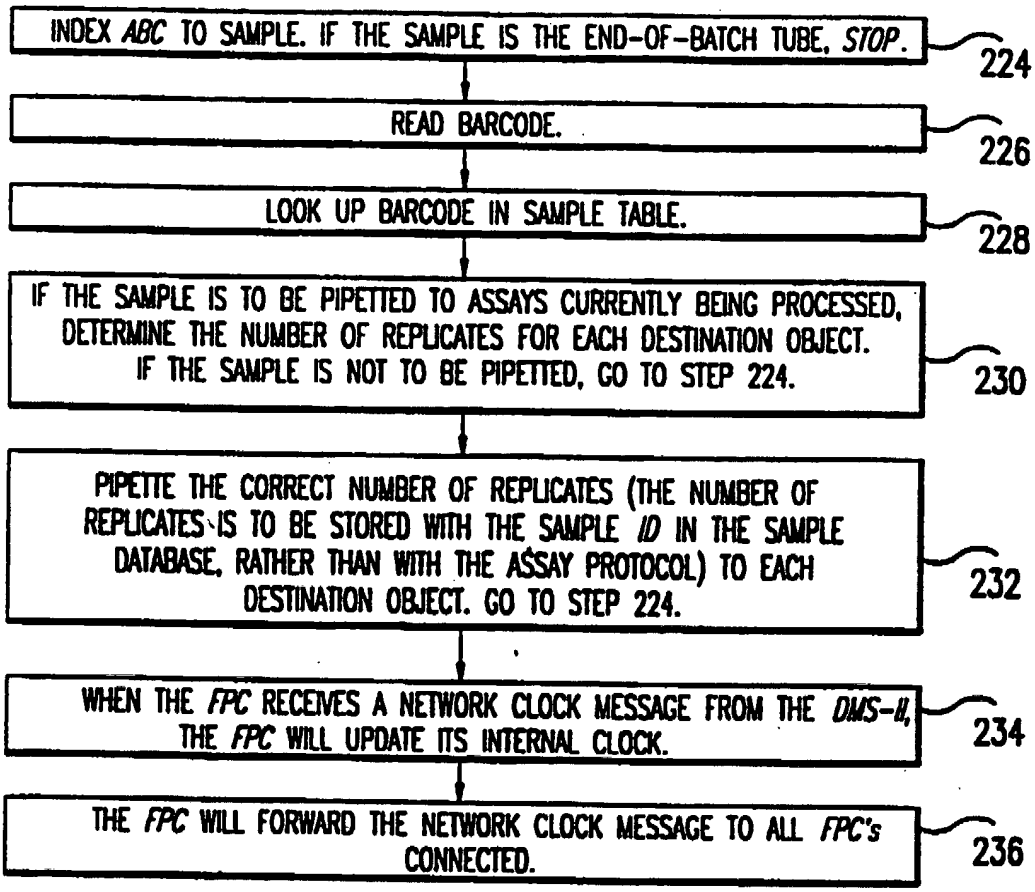
INDEX ABC TO SAMPLE. IF THE SAMPLE IS THE END-OF-BATCH TUBE, STOP.
224
READ BARCODE.
226
LOOK UP BARCODE IN SAMPLE TABLE.
228
IF THE SAMPLE IS TO BE PIPETTED TO ASSAYS CURRENTLY BEING PROCESSED, DETERMINE THE NUMBER OF REPLICATES FOR EACH DESTINATION OBJECT. IF THE SAMPLE IS NOT TO BE PIPETTED, GO TO STEP 224.
230
PIPETTE THE CORRECT NUMBER OF REPLICATES (THE NUMBER OF REPLICATES IS TO BE STORED WITH THE SAMPLE ID IN THE SAMPLE DATABASE, RATHER THAN WITH THE ASSAY PROTOCOL) TO EACH DESTINATION OBJECT. GO TO STEP 224.
232
WHEN THE FPC RECEIVES A NETWORK CLOCK MESSAGE FROM THE DMS-II, THE FPC WILL UPDATE ITS INTERNAL CLOCK.
234
THE FPC WILL FORWARD THE NETWORK CLOCK MESSAGE TO ALL FPC's CONNECTED.
236

FIG.11

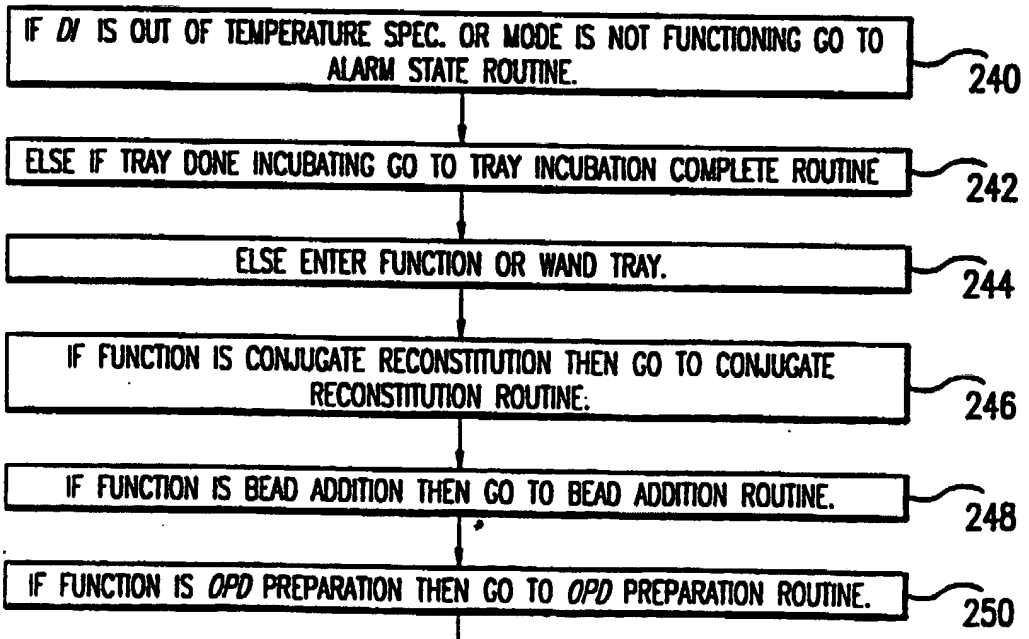
IF DI IS OUT OF TEMPERATURE SPEC. OR MODE IS NOT FUNCTIONING GO TO ALARM STATE ROUTINE.
240
ELSE IF TRAY DONE INCUBATING GO TO TRAY INCUBATION COMPLETE ROUTINE
242
ELSE ENTER FUNCTION OR WAND TRAY.
244
IF FUNCTION IS CONJUGATE RECONSTITUTION THEN GO TO CONJUGATE RECONSTITUTION ROUTINE.
246
IF FUNCTION IS BEAD ADDITION THEN GO TO BEAD ADDITION ROUTINE.
248
IF FUNCTION IS OPD PREPARATION THEN GO TO OPD PREPARATION ROUTINE.
250

FIG.12

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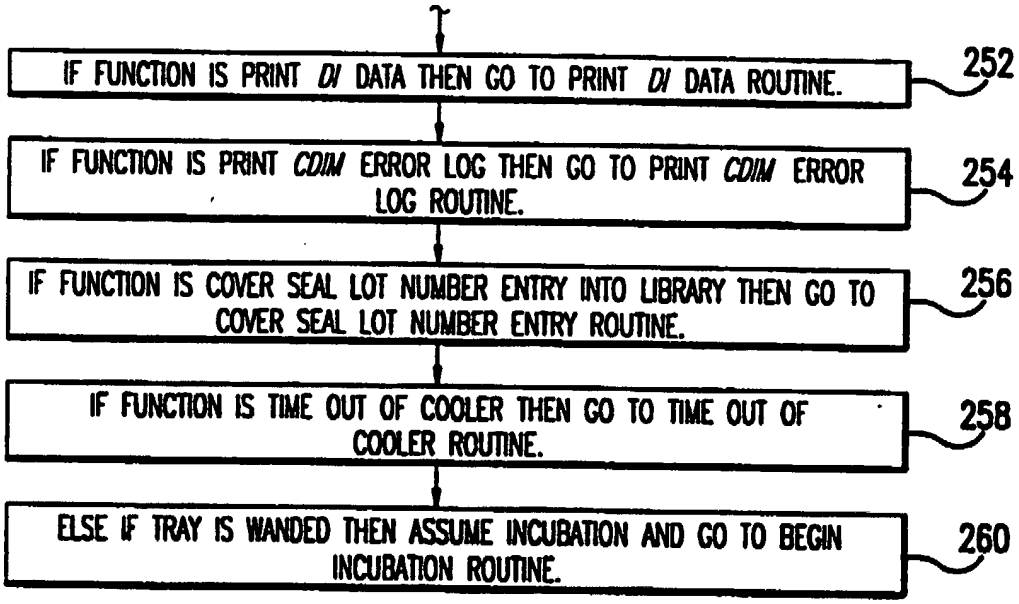

FIG.12 Cont.

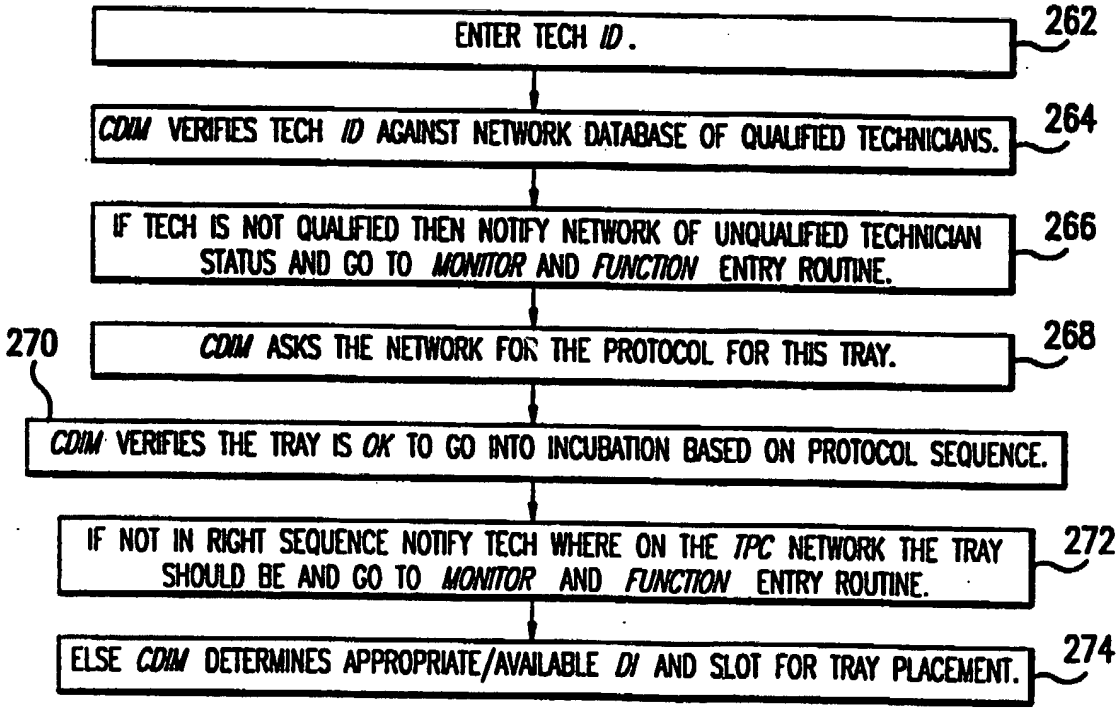

FIG.13a

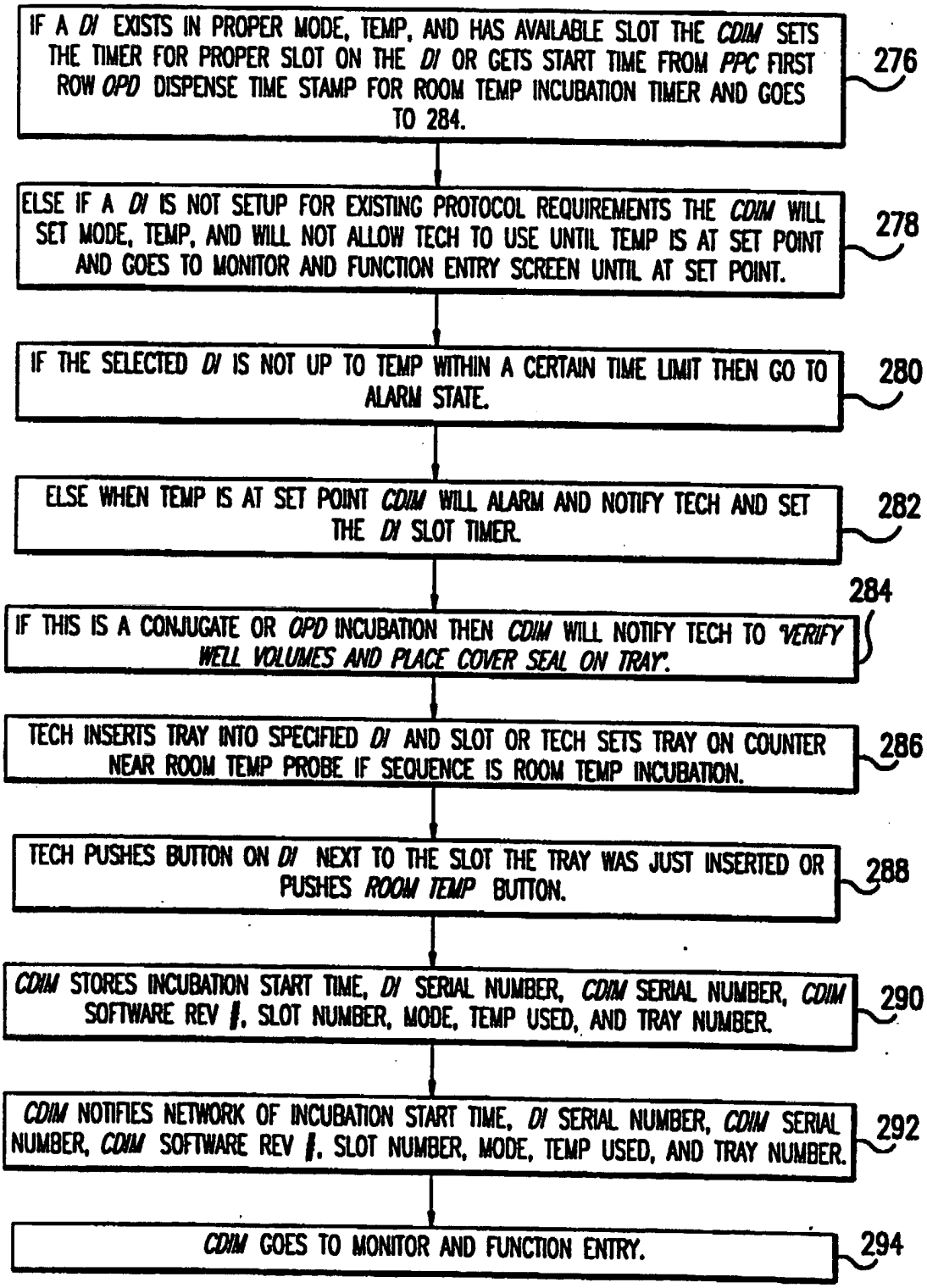
IF A DI EXISTS IN PROPER MODE, TEMP, AND HAS AVAILABLE SLOT THE CDIM SETS THE TIMER FOR PROPER SLOT ON THE DI OR GETS START TIME FROM PPC FIRST ROW OPD DISPENSE TIME STAMP FOR ROOM TEMP INCUBATION TIMER AND GOES TO 284.
276
ELSE IF A DI IS NOT SETUP FOR EXISTING PROTOCOL REQUIREMENTS THE CDIM WILL SET MODE, TEMP, AND WILL NOT ALLOW TECH TO USE UNTIL TEMP IS AT SET POINT AND GOES TO MONITOR AND FUNCTION ENTRY SCREEN UNTIL AT SET POINT.
278
IF THE SELECTED DI IS NOT UP TO TEMP WITHIN A CERTAIN TIME LIMIT THEN GO TO ALARM STATE.
280
ELSE WHEN TEMP IS AT SET POINT CDIM WILL ALARM AND NOTIFY TECH AND SET THE DI SLOT TIMER.
282
284
IF THIS IS A CONJUGATE OR OPD INCUBATION THEN CDIM WILL NOTIFY TECH TO "VERIFY WELL VOLUMES AND PLACE COVER SEAL ON TRAY".
TECH INSERTS TRAY INTO SPECIFIED DI AND SLOT OR TECH SETS TRAY ON COUNTER NEAR ROOM TEMP PROBE IF SEQUENCE IS ROOM TEMP INCUBATION.
286
TECH PUSHES BUTTON ON DI NEXT TO THE SLOT THE TRAY WAS JUST INSERTED OR PUSHES ROOM TEMP BUTTON.
288
CDIM STORES INCUBATION START TIME, DI SERIAL NUMBER, CDIM SERIAL NUMBER, CDIM SOFTWARE REV #, SLOT NUMBER, MODE, TEMP USED, AND TRAY NUMBER.
290
CDIM NOTIFIES NETWORK OF INCUBATION START TIME, DI SERIAL NUMBER, CDIM SERIAL NUMBER, CDIM SOFTWARE REV #, SLOT NUMBER, MODE, TEMP USED, AND TRAY NUMBER.
292
CDIM GOES TO MONITOR AND FUNCTION ENTRY.
294

FIG.13b

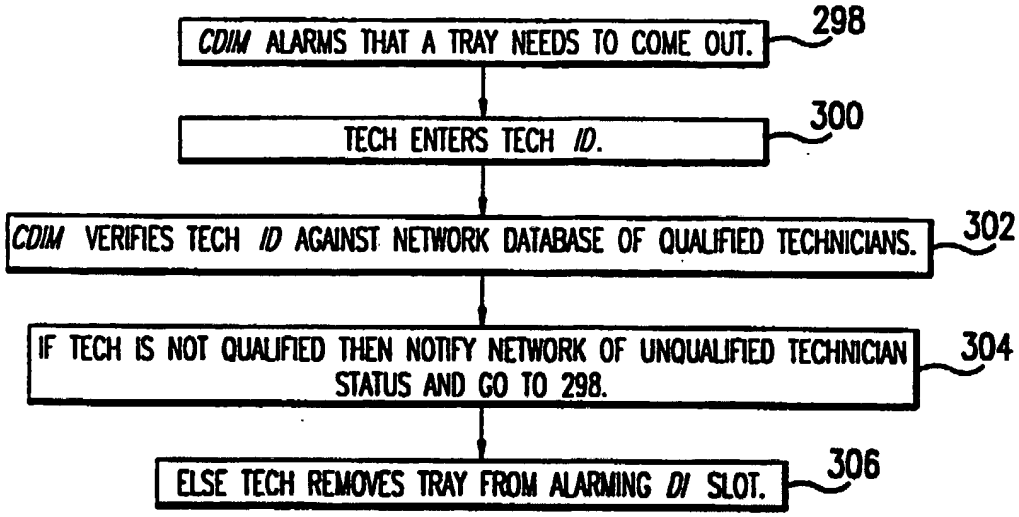

FIG.14a

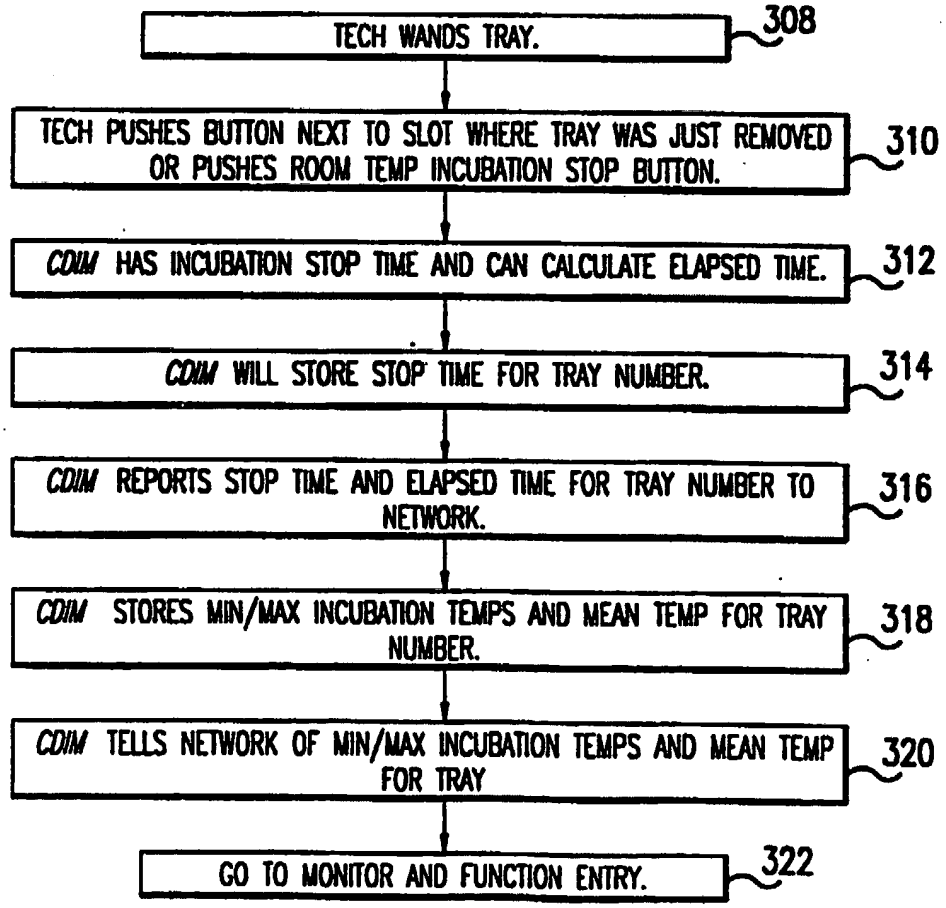

FIG.14b

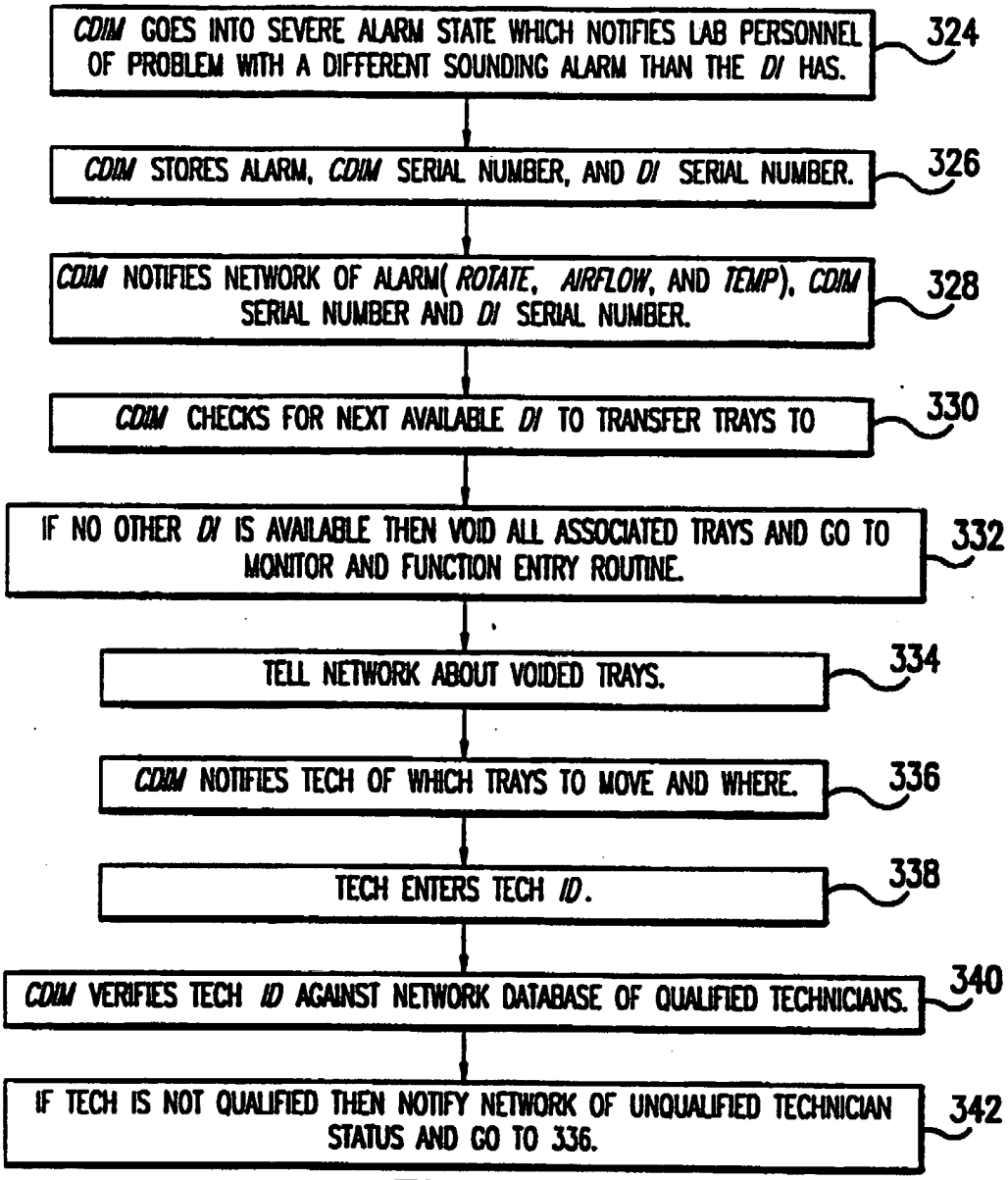

FIG.15a

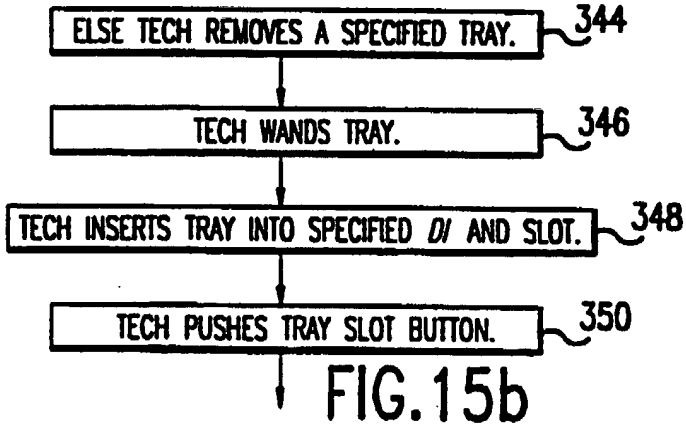

FIG.15b

14/25

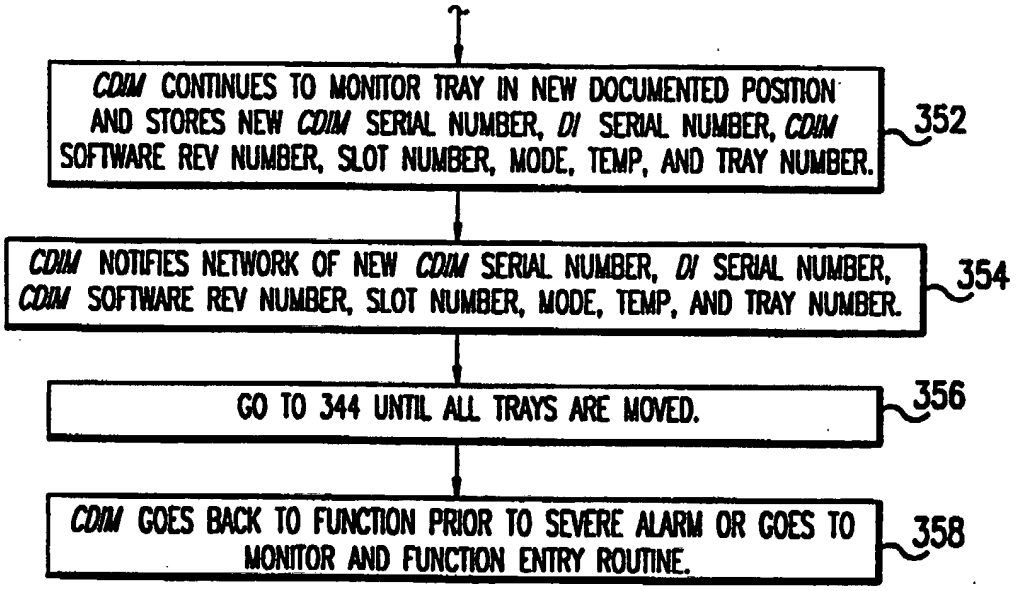

FIG.15b Cont.

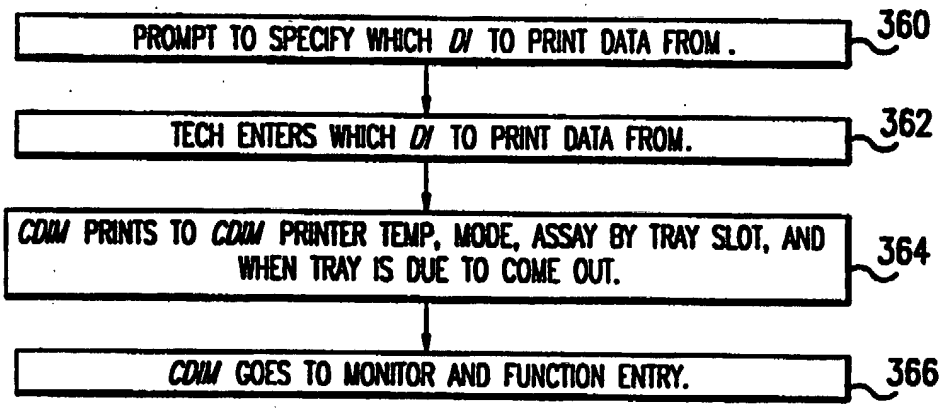

FIG.16

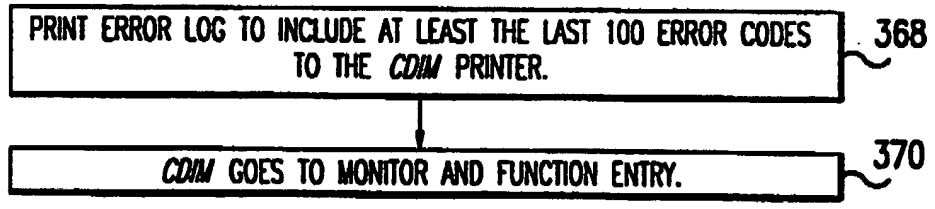

FIG.17

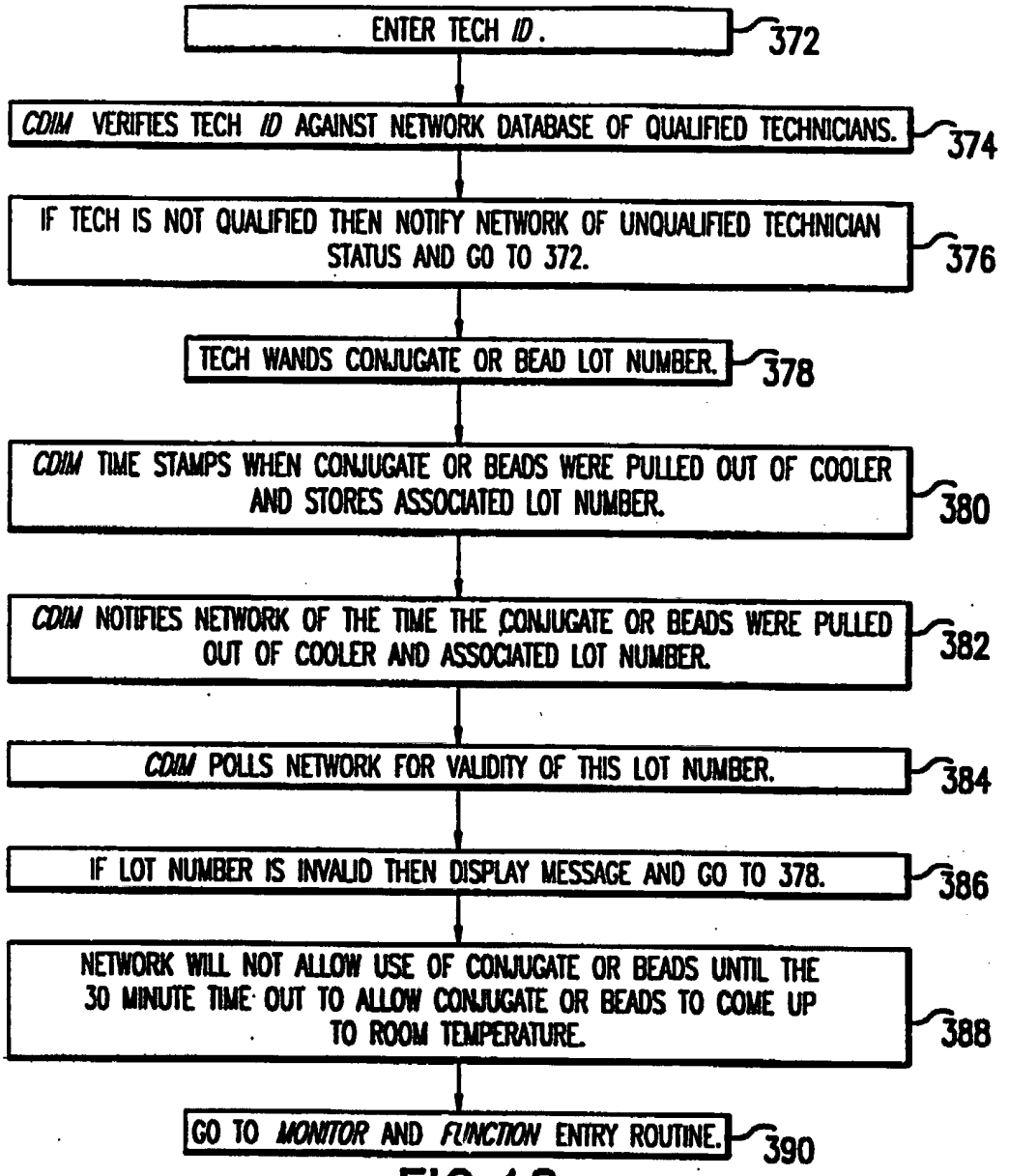
ENTER TECH ID.
372
CDIM VERIFIES TECH ID AGAINST NETWORK DATABASE OF QUALIFIED TECHNICIANS.
374
IF TECH IS NOT QUALIFIED THEN NOTIFY NETWORK OF UNQUALIFIED TECHNICIAN STATUS AND GO TO 372.
376
TECH WANDS CONJUGATE OR BEAD LOT NUMBER.
378
CDIM TIME STAMPS WHEN CONJUGATE OR BEADS WERE PULLED OUT OF COOLER AND STORES ASSOCIATED LOT NUMBER.
380
CDIM NOTIFIES NETWORK OF THE TIME THE CONJUGATE OR BEADS WERE PULLED OUT OF COOLER AND ASSOCIATED LOT NUMBER.
382
CDIM POLLS NETWORK FOR VALIDITY OF THIS LOT NUMBER.
384
IF LOT NUMBER IS INVALID THEN DISPLAY MESSAGE AND GO TO 378.
386
NETWORK WILL NOT ALLOW USE OF CONJUGATE OR BEADS UNTIL THE 30 MINUTE TIME OUT TO ALLOW CONJUGATE OR BEADS TO COME UP TO ROOM TEMPERATURE.
388
GO TO MONITOR AND FUNCTION ENTRY ROUTINE.
390

FIG.18

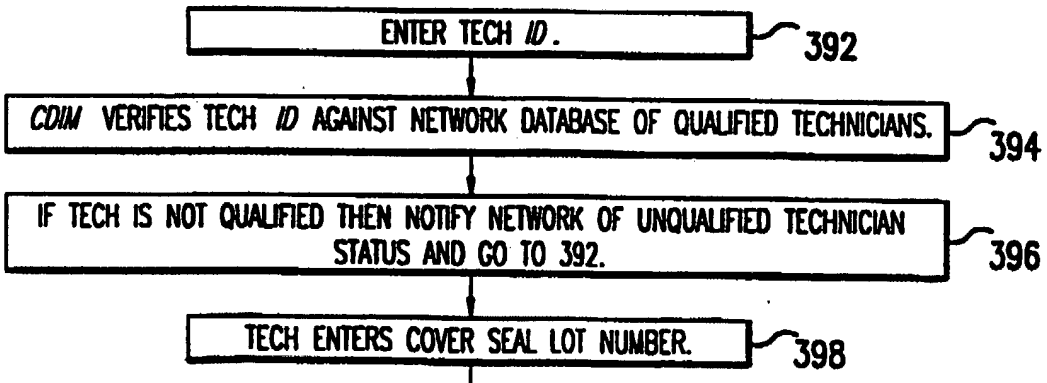
ENTER TECH ID.
392
CDIM VERIFIES TECH ID AGAINST NETWORK DATABASE OF QUALIFIED TECHNICIANS.
394
IF TECH IS NOT QUALIFIED THEN NOTIFY NETWORK OF UNQUALIFIED TECHNICIAN STATUS AND GO TO 392.
396
TECH ENTERS COVER SEAL LOT NUMBER.
398

FIG.19

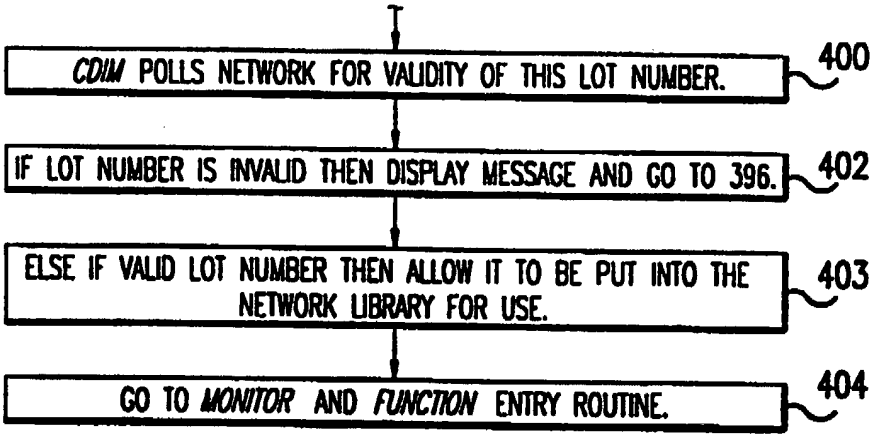

FIG.19 Cont.

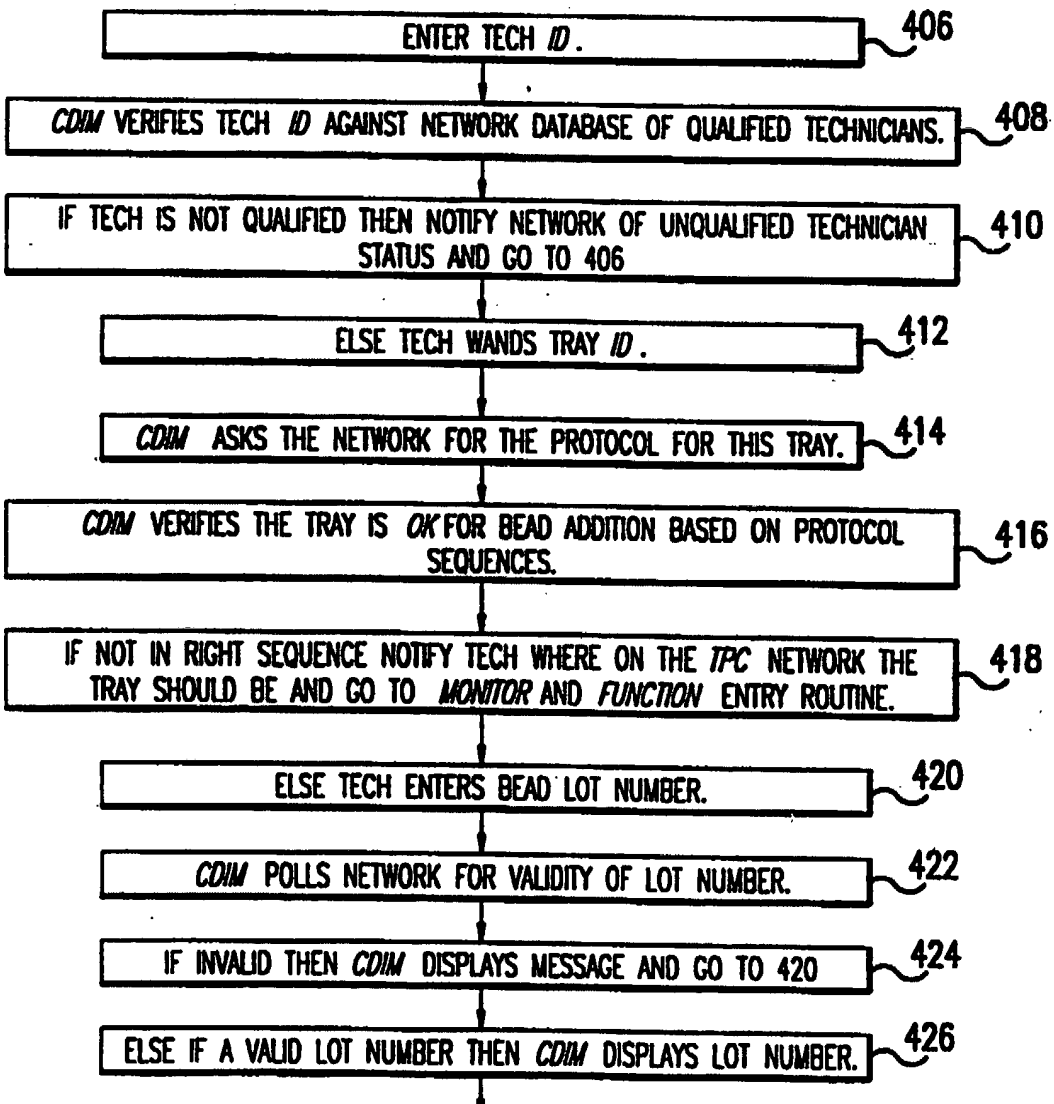

FIG.20a

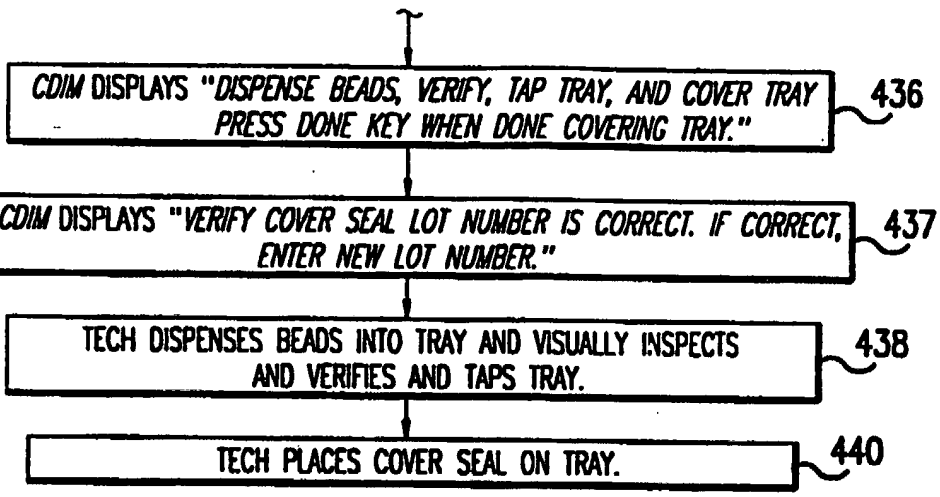

FIG.20a Cont.

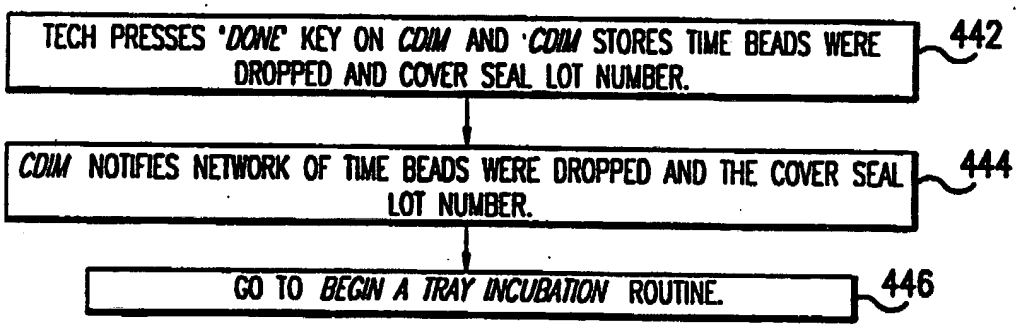

FIG.20b

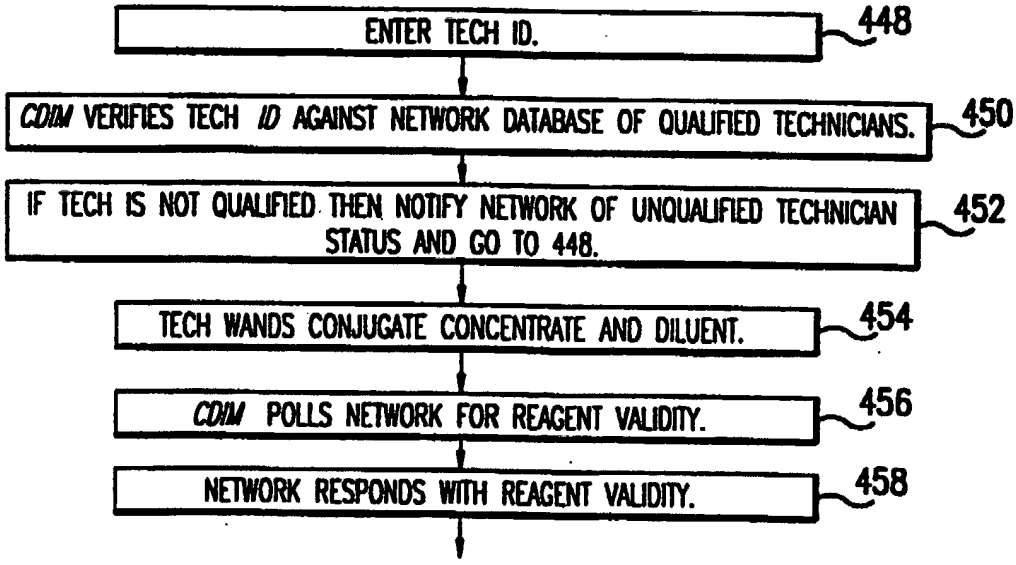

FIG.21a

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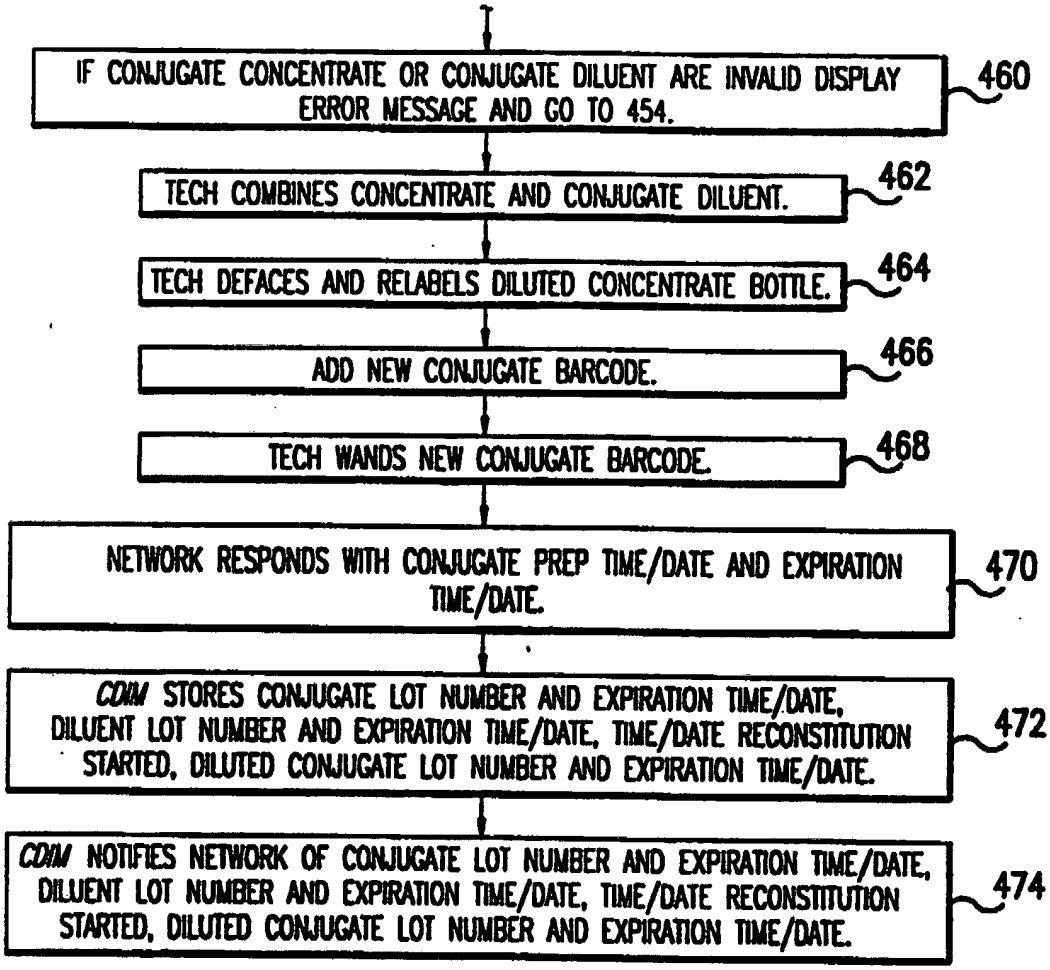

FIG.21a Cont.

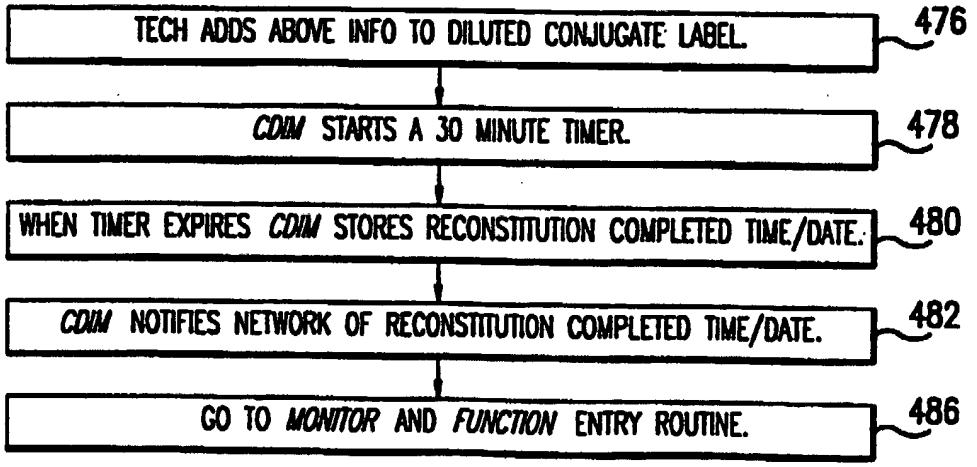

FIG.21b

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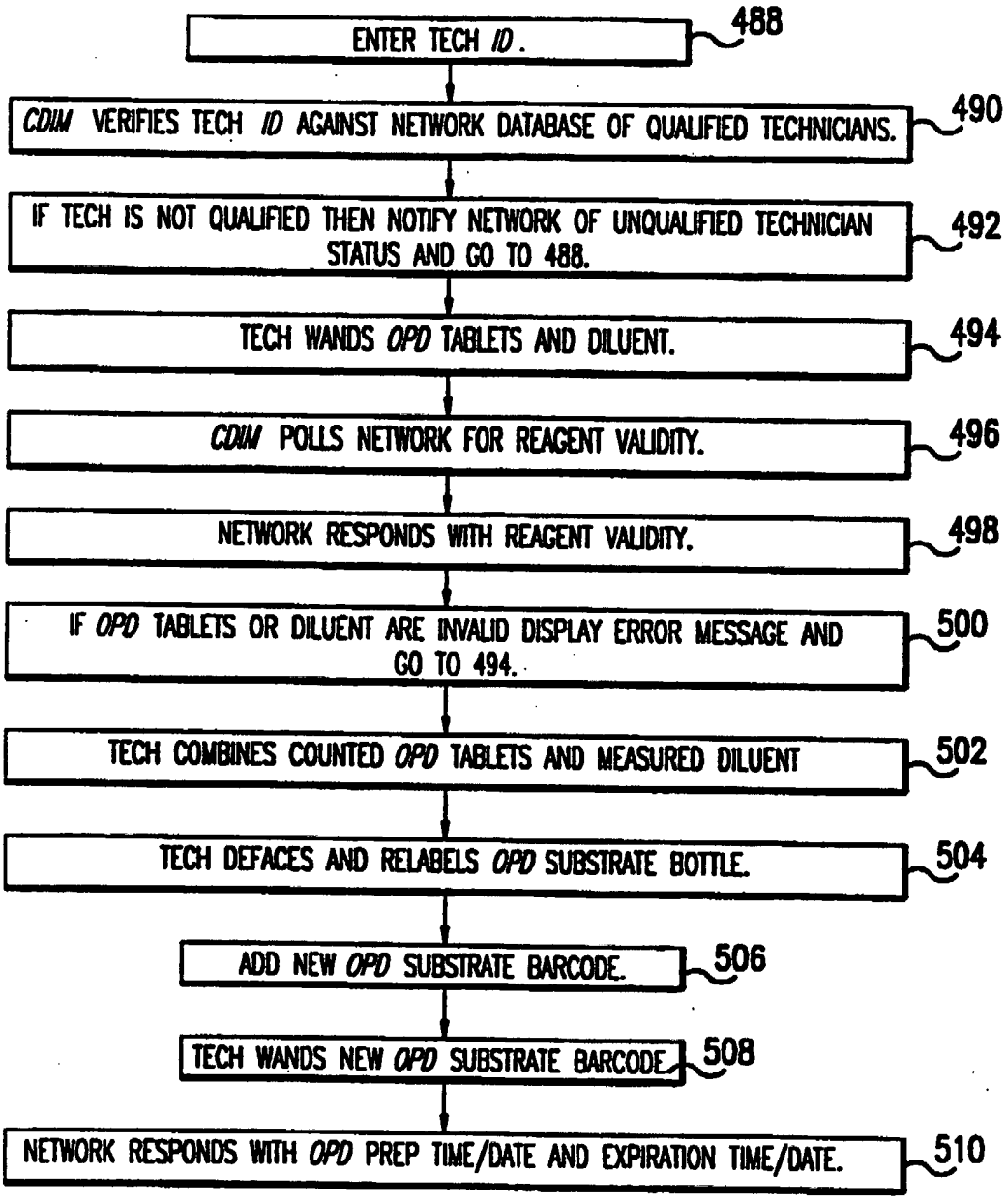
ENTER TECH ID.
488
CDIM VERIFIES TECH ID AGAINST NETWORK DATABASE OF QUALIFIED TECHNICIANS.
490
IF TECH IS NOT QUALIFIED THEN NOTIFY NETWORK OF UNQUALIFIED TECHNICIAN STATUS AND GO TO 488.
492
TECH WANDS OPD TABLETS AND DILUENT.
494
CDIM POLLS NETWORK FOR REAGENT VALIDITY.
496
NETWORK RESPONDS WITH REAGENT VALIDITY.
498
IF OPD TABLETS OR DILUENT ARE INVALID DISPLAY ERROR MESSAGE AND GO TO 494.
500
TECH COMBINES COUNTED OPD TABLETS AND MEASURED DILUENT
502
TECH DEFACES AND RELABELS OPD SUBSTRATE BOTTLE.
504
ADD NEW OPD SUBSTRATE BARCODE.
506
TECH WANDS NEW OPD SUBSTRATE BARCODE.
508
NETWORK RESPONDS WITH OPD PREP TIME/DATE AND EXPIRATION TIME/DATE.
510

FIG.22a

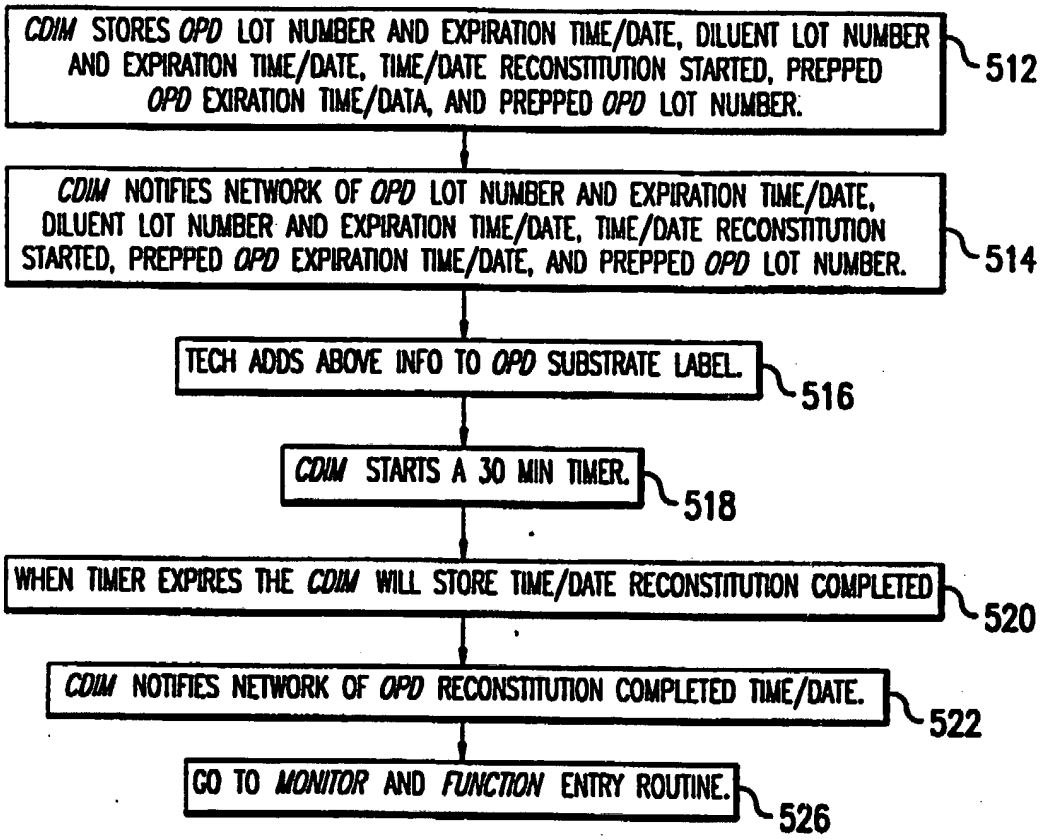

FIG.22b

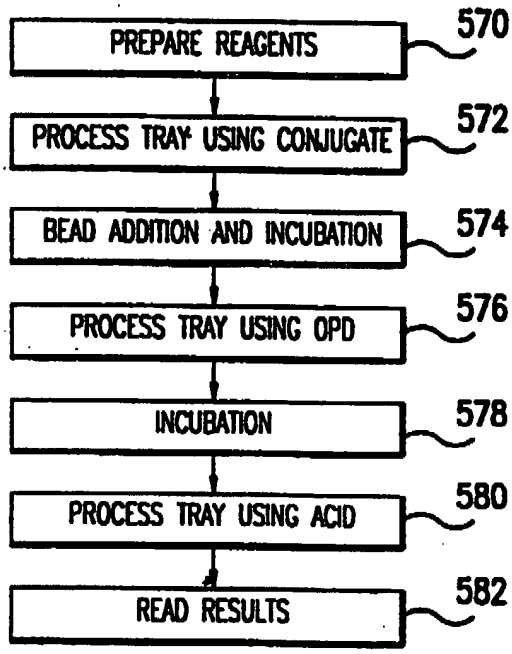

FIG.23

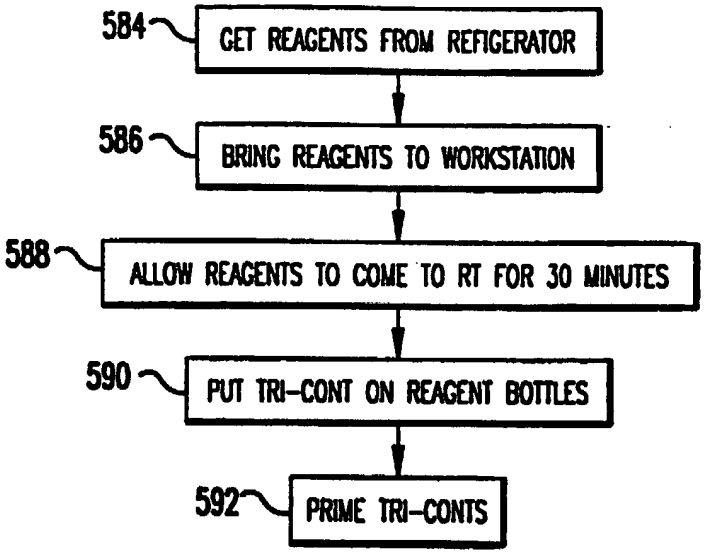

FIG.24

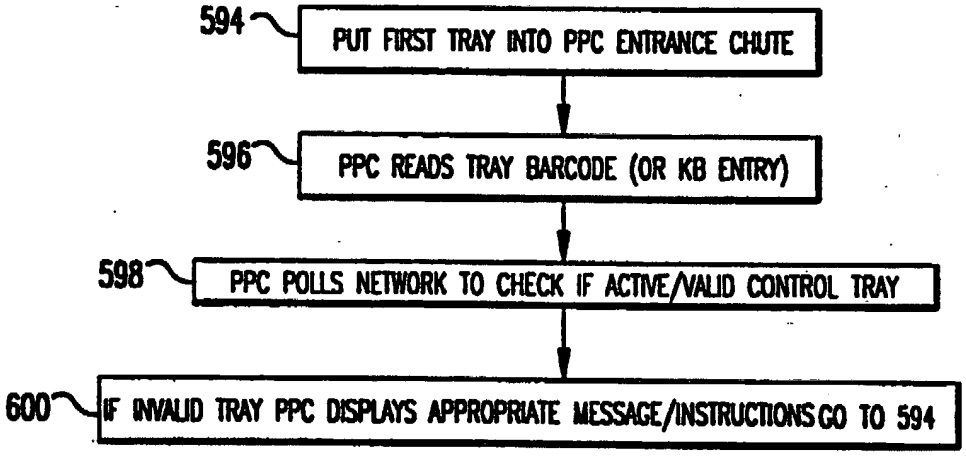

FIG.25

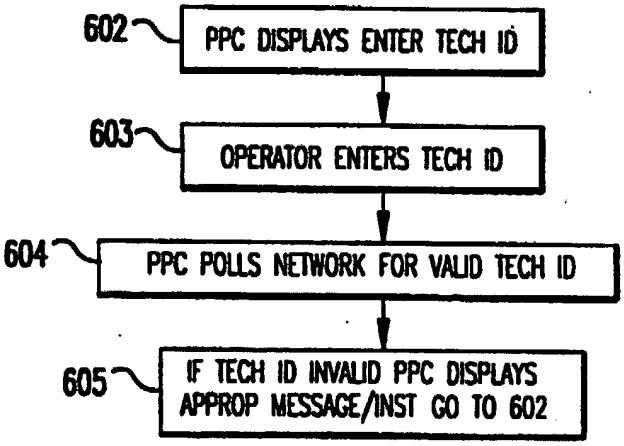

FIG.26

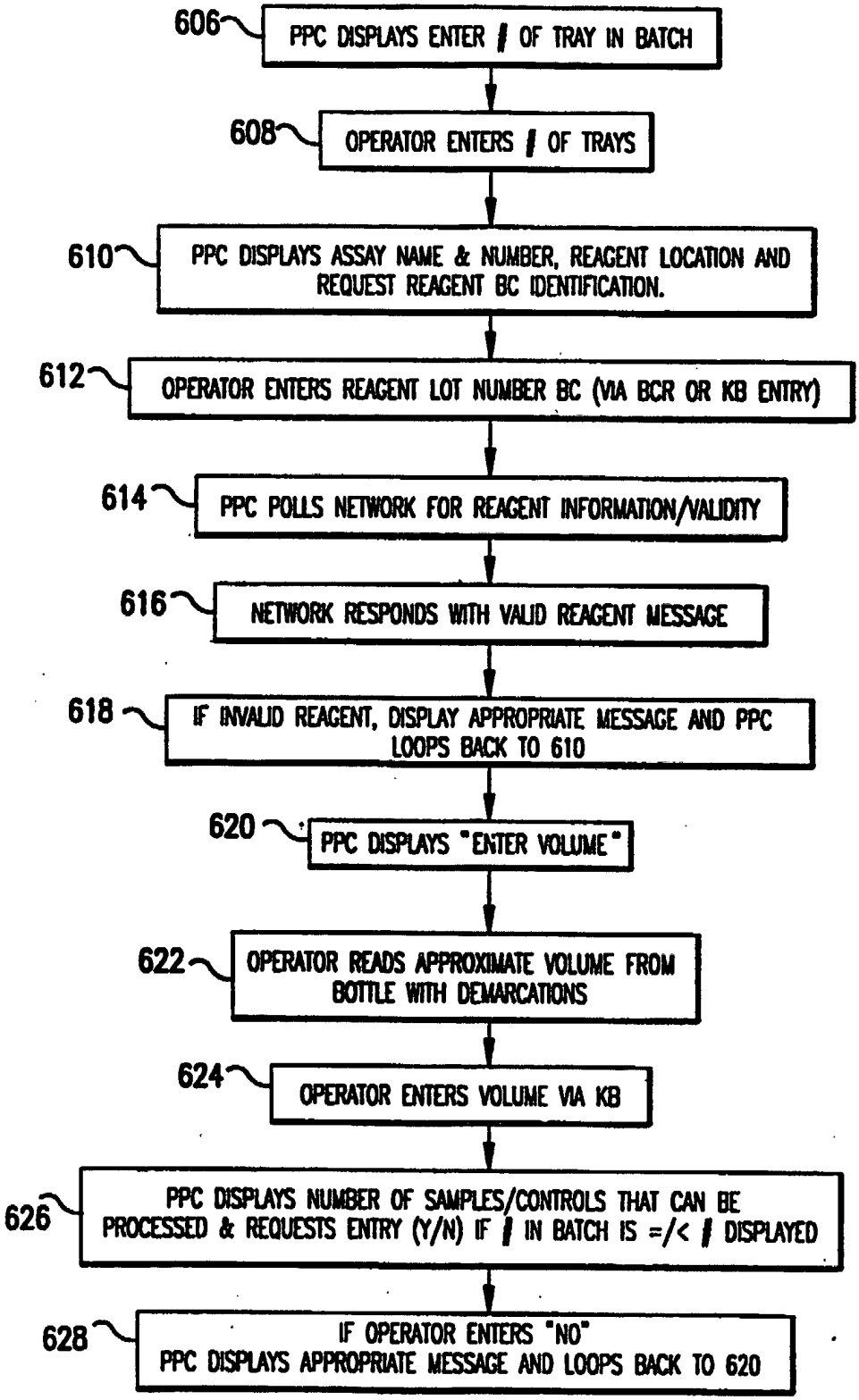
606
PPC DISPLAYS ENTER # OF TRAY IN BATCH
608
OPERATOR ENTERS # OF TRAYS
610
PPC DISPLAYS ASSAY NAME & NUMBER, REAGENT LOCATION AND REQUEST REAGENT BC IDENTIFICATION.
612
OPERATOR ENTERS REAGENT LOT NUMBER BC (VIA BCR OR KB ENTRY)
614
PPC POLLS NETWORK FOR REAGENT INFORMATION/VALIDITY
616
NETWORK RESPONDS WITH VALID REAGENT MESSAGE
618
IF INVALID REAGENT, DISPLAY APPROPRIATE MESSAGE AND PPC LOOPS BACK TO 610
620
PPC DISPLAYS "ENTER VOLUME"
622
OPERATOR READS APPROXIMATE VOLUME FROM BOTTLE WITH DEMARCATIONS
624
OPERATOR ENTERS VOLUME VIA KB
626
PPC DISPLAYS NUMBER OF SAMPLES/CONTROLS THAT CAN BE PROCESSED & REQUESTS ENTRY (Y/N) IF # IN BATCH IS =/< # DISPLAYED
628
IF OPERATOR ENTERS "NO" PPC DISPLAYS APPROPRIATE MESSAGE AND LOOPS BACK TO 620

FIG.27a

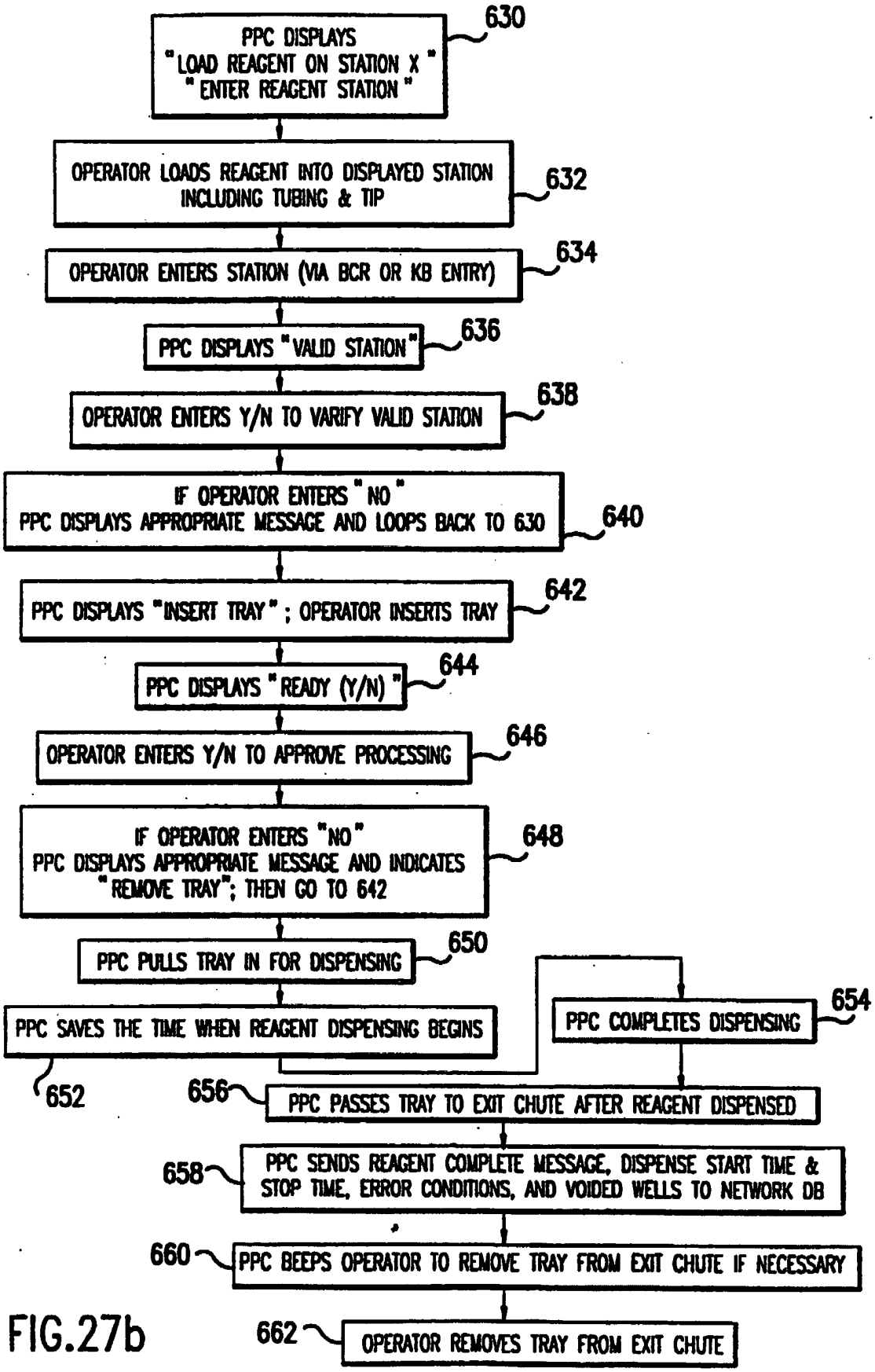
PPC DISPLAYS "LOAD REAGENT ON STATION X" "ENTER REAGENT STATION"
630
OPERATOR LOADS REAGENT INTO DISPLAYED STATION INCLUDING TUBING & TIP
632
OPERATOR ENTERS STATION (VIA BCR OR KB ENTRY)
634
PPC DISPLAYS "VALID STATION"
636
OPERATOR ENTERS Y/N TO VARIFY VALID STATION
638
IF OPERATOR ENTERS "NO" PPC DISPLAYS APPROPRIATE MESSAGE AND LOOPS BACK TO 630
640
PPC DISPLAYS "INSERT TRAY"; OPERATOR INSERTS TRAY
642
PPC DISPLAYS "READY (Y/N)"
644
OPERATOR ENTERS Y/N TO APPROVE PROCESSING
646
IF OPERATOR ENTERS "NO" PPC DISPLAYS APPROPRIATE MESSAGE AND INDICATES "REMOVE TRAY"; THEN GO TO 642
648
PPC PULLS TRAY IN FOR DISPENSING
650
PPC SAVES THE TIME WHEN REAGENT DISPENSING BEGINS
652
PPC COMPLETES DISPENSING
654
656
PPC PASSES TRAY TO EXIT CHUTE AFTER REAGENT DISPENSED
658
PPC SENDS REAGENT COMPLETE MESSAGE, DISPENSE START TIME & STOP TIME, ERROR CONDITIONS, AND VOIDED WELLS TO NETWORK DB
660
PPC BEEPS OPERATOR TO REMOVE TRAY FROM EXIT CHUTE IF NECESSARY
662
OPERATOR REMOVES TRAY FROM EXIT CHUTE

FIG.27b

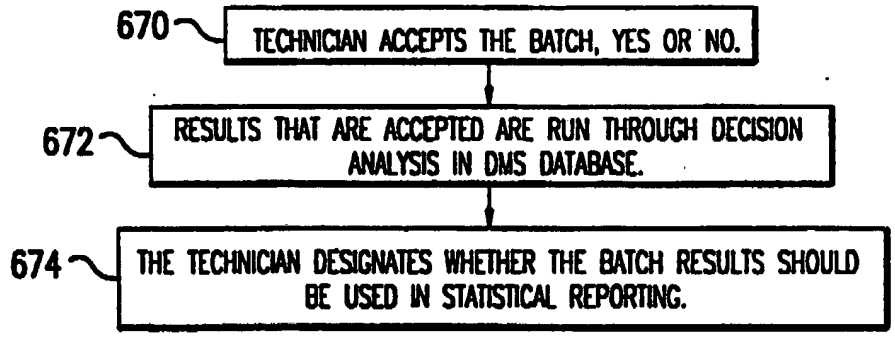

FIG.28

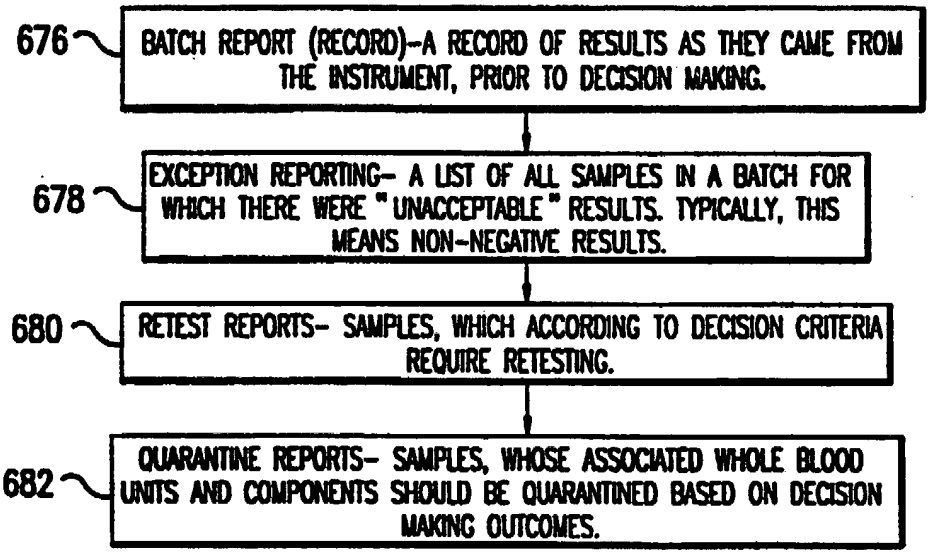

FIG.29

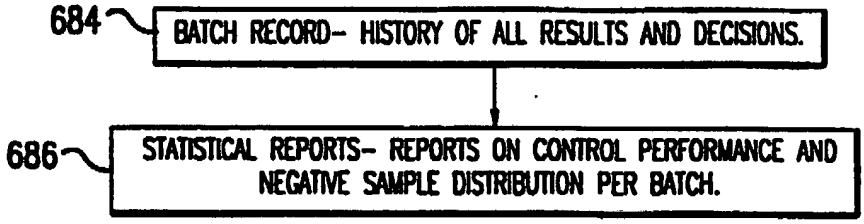

FIG.30

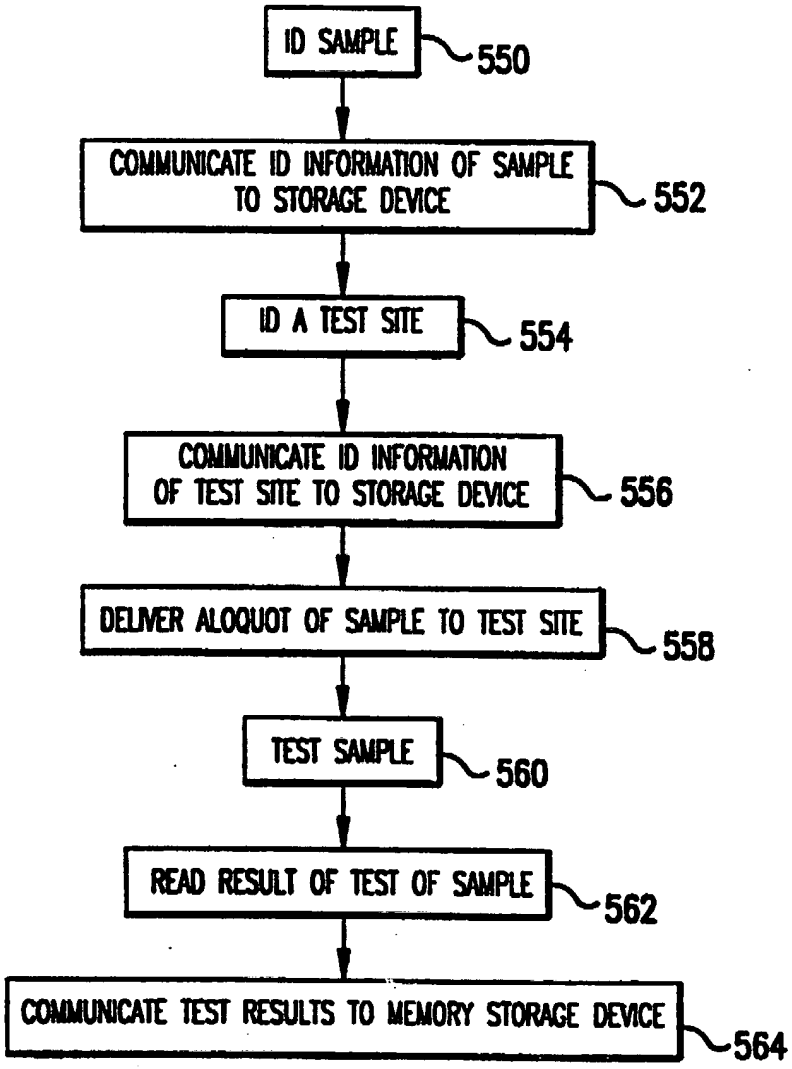
ID SAMPLE
550
COMMUNICATE ID INFORMATION OF SAMPLE TO STORAGE DEVICE
552
ID A TEST SITE
554
COMMUNICATE ID INFORMATION OF TEST SITE TO STORAGE DEVICE
556
DELIVER ALOQUOT OF SAMPLE TO TEST SITE
558
TEST SAMPLE
560
READ RESULT OF TEST OF SAMPLE
562
COMMUNICATE TEST RESULTS TO MEMORY STORAGE DEVICE
564

FIG.31

INTERNATIONAL SEARCH REPORT

Inter[illegible]onal application No.
PCT/US93/10525

A. CLASSIFICATION OF SUBJECT MATTER
IPC(5) :G06F 15/42
US CL : 364/413.01
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 364/413.01, 413.07, 413.08, 413.09, 413.10, 413.11, 468, 478, 497, 500

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y, P	US, A, 5,231,585 (Kobayashi et al) 27 July 1993, abstract and figs. 1, 13-16B.	1-7
A, E	US, A, 5,282,139 (Kobayashi) 25 January 1994, abstract and fig. 1.	1-7
A,E	US, A, 5,282,149 (Grandone et al) 25 January 1994, abstract and fig. 1.	1-7
A	US, A, 5,122,342 (McCulloch et al) 16 June 1992, abstract and figs. 1-2.	1-7
A, E	US, A, 5,273,392 (Bernard, II et al) 28 December 1993, abstract and figs. 2 and 41-42.	1-7

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 13 APRIL 1994	Date of mailing of the international search report 25 APR 1994
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. N.A.	Authorized officer ROBERT WEINHARDT Telephone No. (703) 305-9780

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INTERNATIONAL SEARCH REPORT

Inter. onal application No.
PCT/US93/10525

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,857,716 (Gombrich et al) 15 August 1989, abstract, figs. 1, 14-15 and col. 8 line 8 to col. 9 line 40.	1-7
A,E	US, A, 5,260,872 (Copeland et al) 09 November 1993, abstract.	1-7
A, P	US, A, 5,197,011 (Biemans et al) 23 March 1993, abstract and fig. 1.	1-7